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INTEGRATION OF INFORMATION FOR HOSPITAL RATE SETTING

VOLUME 1: DISCLOSURE OF PSRO INFORMATION TO HOSPITAL RATE SETTING BODIES: A LEGAL ANALYSIS

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INTEGRATION OF INFORMATION FOR HOSPITAL RATE SETTING

VOLUME 1: DISCLOSURE OF PSRO INFORMATION TO HOSPITAL RATE SETTING BODIES: A LEGAL ANALYSIS

by

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INTRODUCTION

Hospital rate setting is a new type of regulatory activity in the United States. Between 1970-1975, in an attempt to control the extraordinary rise in hospital costs, the number of rate setting programs grew from two to twenty-seven. These programs now control the hospital rates or charges to one or more major types of payers in twenty-three states. State agencies have legally mandated rate setting authority in nine of these states; most of the other rate setting activity is conducted by Blue Cross plans.

Professional Standards Review Organizations (PSROs), another new type of control activity, were also established in response to the problem of rising hospital costs. This paper examines some possible obstacles to the sharing of patient casemix and related types of data between PSROs and rate setting bodies in the light of some apparent conflicts in Congressional intent embodied in several recently enacted laws.

The paper is the first of a series of working papers in a project whose task is to explore the types of information required to permit equitable hospital rate setting, and the obstacles to its access, integration and use.* The project is attempting to identify the general scope of information required for rate setting, rate appeals and program evaluation, the problems of data quality, and the availability of resources required to analyze the data. It also identifies points of potential linkage with other agencies that might need the same types of data, although at different levels of aggregation. Most of the working papers examine

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different types of specific obstacles that appear to interfere with rate setters' access to the required data, or that appear to impede their efforts to improve its quality and usefulness.

The methodology for hospital rate setting is still at the toddler stage, if not still in infancy. It is handicapped by serious inadequacies in the information base, now derived almost exclusively from expenditure and revenue data collected from individual hospitals, together with gross counts of their activities, using measures such as numbers of patient days, numbers of tests performed, and so forth. Information to show differences among hospitals in respect to the characteristics of the patients they treat, and the complexity of the medical problems these patients present, is at present almost entirely absent from the rate decision-making process. Yet analyses of cost functions in the hospitals of two Canadian provinces, Ontario and British Columbia, where such patient-related data is available, show that the pattern of discharge diagnoses is the crucial determinant of inter-hospital variations in cost per case and per day, and that the age-sex pattern of discharges plays a secondary but also significant role.*

The penalties attendant on poor data are high. Lacking information that explains legitimate cost differences among hospitals, rate reviewers may inadvertantly set too high a rate in some hospitals in relation to the services they actually render their patients and the populations they serve, thereby underwriting either operating or system inefficiencies. In other hospitals they may set too low a rate, thereby threatening the provision of useful services to patients, stimulating appeals, litigation, and other types of defensive actions.

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* Robert G. Evans, Hugh D. Walker, "Information Theory and the Analysis of Hospital Cost Structure", Canadian Journal of Economics, Vol. V, No. 3, August, 1972, p. 417.

Casemix data are also important to monitor changes in a hospital over time. The rates set from year to year should take account of whether through referrals of difficult cases, its physicians come to provide a greater predominance of primary care.

For these and similar purposes, rate setting bodies at a minimum need from each hospital annual statistics on its mix of patients by age, sex, diagnosis and case complexity, together with an overview of the numbers and types of most commonly performed tests and surgical procedures, again by age and sex. These types of data need to be related to patient management information reflected in length of stay and other utilization indicators.

Finally, in order to make informed decisions in conjunction with planning agencies about the desirability of increasing a hospital's rates to support proposed new programs and facilities (and/or whether to continue to subsidize underutilized programs and facilities through the rate), the rate setting body needs to be able to study utilization patterns in the total population of the geographic area where each hospital is located. It will also want to learn the extent of each hospital's dependency on its particular service area, and the extent of that population's dependency on the hospital.

Most of the data items needed to construct such information are included on the Uniform Hospital Discharge Data Set endorsed by the American Hospital Association and by the Bureau of Quality Assurance and Social Security Administration of the Department of Health, Education and Welfare. The more than 200 PSROs that are due to be in operation by July 1976 will base their determinations of quality and medical necessity on a specified

set of these data items, which will be collected from hospitals on discharge abstract forms filled out for each Medicare and Medicaid patient. Currently, the abstracts will only be collected for these and other patients whose care is paid for under the Social Security Act, but it seems likely that Blue Cross plans and hospital associations will push for similar abstracts for all patients discharged from hospitals since they too have needs for better patient related data.

While the enabling laws that create state rate setting commissions often give them authority to collect directly from hospitals any information they require, this is not always the case. Even where rate setting bodies have the legal authority to collect patient related hospital data, however, the public should not be asked to pay for the expense of creating duplicate information systems. For both these reasons, rate setting bodies should seek access to hospital casemix profiles directly from the PSROs or from the intermediary organization that stores them.

A single shared effort for data collection and processing of the discharge data set from each hospital in a given geographic area would appear to serve the needs of PSROs, rate setters, planners and other users at least expense and with least added burden to hospitals. Moves to establish user consortiums for the UHDDS were being made in several states as this paper was being written.* However, some PSROs and PSRO organizations appear to be reluctant to share control over access to the data sets. Thus, legal problems at both the state and federal level are posed.

* Maryland, New York, Massachusetts, New Jersey and Washington are states where rate setting bodies are participating actively in the effort.

Must PSROs disclose these profile reports to state rate setting bodies, or can they decide to withhold such disclosure? On August 31, 1975, a policy statement by the American Association of Foundations for Medical Care, a national organization serving as spokesman for many PSROs, took the position that individual PSROs should have wide discretion to determine what information they would disclose to whom, when and at what price.* Would rate setting bodies be able to use legal means to obtain access?

This paper discusses these questions in the light of present federal laws and proposed regulations. Part I presents a summary and conclusions; Part II describes the relevant disclosure provisions of the 1972 Social Security Act amendment that established PSROs, and the proposed regulations to implement these provisions; Part III reviews the possible applications of the federal Freedom of Information Act; and Part IV deals with the possible applications of the federal Privacy Act of 1974.

The paper was written in August 1975 during a time when the question of who is to collect the uniform hospital discharge data set was still unresolved. Although there are many potential users of the UHDDS, the PSROs' needs for it are the most acute since the law requires that they begin operations by July 1, 1976. PSROs that already have a conditional status are even more pressed; they must start functioning by January 1, 1976. For this reason, the argumentation to follow is posited on the proposition that the PSROs will indeed be able to collect the data they need and that rate setting bodies will be seeking ways to obtain access. Should the data set in fact be collected by some other organization, the disclosure problems may be quite different.

Katharine G. Bauer

*American Association of Foundations for Medical Care News Letter, 8/31/75.

I. SUMMARY AND CONCLUSIONS

Although PSRO information might satisfy certain important information needs of rate-setting bodies, the PSRO law heavily circumscribes the realms of permissible PSRO disclosure. The Secretary of HEW must promulgate regulations governing PSRO disclosure; depending on how they are written, these regulations may permit rate setters to use PSRO statistical data, and even may give rate-setters access to information that identifies individual patients or doctors. However, a conclusive analysis of PSRO disclosure must await the publication of the final version of the regulations.

Even if the regulations narrowly restrict access to PSRO data, rate-setting bodies still may be able to use the federal Freedom of Information Act to obtain statistical information from PSROs. However, rate-setting bodies can use that Act only if they are not defined as federal "agencies"; the Act will apply to PSROs only if they are federal agencies. The Privacy Act of 1974 conceivably could, but probably will not, limit PSRO disclosure.

Disclosure Under the PSRO Statute and the Proposed HEW Regulations

The PSRO statute permits PSRO disclosure only 1) to the extent necessary to carry out the purposes of the law, or 2) as the Secretary of HEW provides by regulation to protect the "rights and interests" of patients and providers. The PSRO law also directs the

Secretary to provide for the inter-agency transfer of data, but he has interpreted this command as a special case of his general power under the PSRO law to promulgate regulations. The Secretary has circulated a tentative version of the PSRO regulations governing inter-agency disclosure.

The proposed regulations (draft, February, 1975) define a "PSRO review system" whose components will share any PSRO data they need in the performance of their duties. Agencies within the "PSRO review system" may share even "privileged" information, but agencies outside the system can get only non-privileged information. Any information that identifies an individual, patient or doctor, or has been gathered for Medical Care Evaluation studies, is "privileged" under the proposed regulations.

The proposed regulations** define the "PSRO review system" to include agencies that receive PSRO data for administrative purposes under Titles 5, 18, or 19 of the Social Security Act. In the perspective of the statute as written, however, the proposed regulations appear to be taking too narrow a view of the kinds of agencies that may qualify. It is not clear whether rate setting bodies would be part of the "system", although Congress explicitly required the Secretary to promulgate regulations providing for the interchange of data between PSROs and agencies having "review or control" functions. Congress further required that those agencies use PSRO data in a manner consistent with the effective implementation of the PSRO law, and that the agencies receive the data under Titles 5, 18, or 19 of the Social Security Act.

**See Appendix I. HEW has circulated a tentative version of the PSRO disclosure regulations. These tentative regulations have not been formally promulgated, nor has HEW issued a Notice of Proposal Rule-making concerning them. Indeed HEW calls these tentative regulations "policy statements". However, it is very likely that the final regulations will closely resemble the "policy statements".

Rate setting agencies could argue that they should fit into the Congressional definition of the group of agencies that should share PSRO data. Since rate setting is the quintessential 'control' function, rate setting bodies would satisfy the first Congressional criterion. Since hospitals must provide data to PSROs if the hospitals are to participate in Medicare or Medicaid, rate setters' use of PSRO information should not undermine the implementation of the PSRO law. Rate setters that share data under Titles 5, 18 or 19 of the Social Security Act will meet the third Congressional criterion. Therefore, rate-setting bodies should share PSRO information.

The proposed regulations, however, are not clear on the matter. Rate setting bodies may or may not be defined as falling within the definition of the "PSRO review system". If they are defined as agencies outside the system, their access even to statistical reports is somewhat in doubt. However, while the regulations fail to contain any direct statement relating to disclosure of statistical data that do not identify individual doctors or patients, or that has been gathered for the purpose of Medical Care Evaluation studies, several of the provisions taken together can be construed to show the intention of providing such access. In any event, no agencies outside the PSRO review system would be able to get "privileged information".

Should rate setting bodies be unable to get access to statistical reports on hospital casemix under the PSRO regulations, they may seek other means to obtain such information.

Disclosure Under the Freedom of Information Act

The federal Freedom of Information Act (FIA) might prove to be the means for rate setters to gain access. However, the FIA will apply to PSROs only if they are defined as federal agencies - that is, only if the PSROs have significant authority derived from federal law. Rate setters, on the other hand, may use the FIA only if they are not defined as federal agencies. Rate setters must have state statutory authority - or very indirect federal authority - before they can use the FIA.

The FIA compels agencies to release their records upon request by any person or organization other than a federal agency, unless the records fall within one of nine exemptions enumerated in the FIA. Four of these exemptions might pertain to PSRO disclosure to rate setting bodies:

- matters whose disclosure is forbidden by statute;
- confidential commercial information;
- inter-agency memoranda;
- files whose disclosure would constitute a "clearly unwarranted" invasion of privacy.

Rate setting bodies could argue that none of those exemptions applies to their request for PSRO data. Since the PSRO statute permits disclosure to the extent necessary to carry out the purposes of the PSRO law, any agency that carries out those purposes should share PSRO data. A rate setter dedicated to containing costs with-

out sacrificing quality would pursue exactly the purposes of the PSRO law. The limitation on PSRO disclosure, therefore, should not apply to rate setters, and the first exemption mentioned above should not block disclosure under the FIA.

Rate setters also could argue that PSRO statistical information is not "commercial" under the FIA, and that even if it is commercial, it is not "privileged or confidential" - thus avoiding the second exemption mentioned above. Since rate setters will ask only for statistical data, they will avoid the third possibly applicable exemption. Finally, rate setters would argue that their use of PSRO data would guard, if not advance, the public interest. Thus, even if the provision of PSRO information invaded the personal privacy of doctors or patients, the invasion would not be "clearly unwarranted."

Disclosure Under the Privacy Act

The Privacy Act of 1974 should pose no problem for rate setters. The Act probably will apply to PSROs, but probably does not apply to the PSRO statistical information that rate setters will seek. Even if the Act did apply to those records, four exceptions in the Act might permit rate setters to use PSRO data, regardless of the legal form that rate setters take. If rate setting authority belongs to the same federal agency as PSROs, rate setters can use PSRO data to perform their duties as a federal authority. If rate setters exist

in a separate federal agency, PSROs may give them data for "routine uses" - which rate setting presumably would be. If rate setters are a state agency, or even a private organization, they may use the FIA to get PSRO information; the Privacy Act creates no additional barriers to disclosure under the FIA. A non-federal rate setter, unable to use the FIA, would rely on the exception for "statistical records"; the rate setters only would guarantee not to "make determinations" about individuals - but could make them about hospitals.

The statutory basis for rate setting, then, and not the level of political organiztion, plays the most important role in determining whether rate setting bodies can obtain PSRO information. Statutory authority or information-sharing under the Social Security Act will benefit rate setters most if they seek PSRO information under the disclosure regulations as part of the "PSRO review system". State statutory authority would help them get PSRO information by using the Freedom of Information Act. State or local rate setting bodies might be able to get PSRO data through FIA even if federal law directly authorized or encouraged their functions, as under the Social Security Act's Section 222 experiments, but they would have to demonstrate that they were not federal "agencies".

Nonetheless, if some or all of the PSROs oppose sharing their information, long delays can be expected while litigation resolves the many cloudy legal issues suggested here and noted more fully in the body of this paper. Therefore, unless final HEW regulations on PSRO

disclosure are very specific on information sharing policies, it may be best to seek some specific statutory authority from Congress requiring PSROs to share their data with local rate setting bodies. This, of course, could simply follow the precedent already established in P.L. 93-641, the 1974 Planning Law, which requires PSROs to share their data with local planning agencies.

Rate setters probably face the greatest obstacles in surmounting the tremendous discretion that rests with various federal officials and the numerous, independent PSROs. Rate setters can present persuasive arguments that they should partake of the flow of PSRO information, but they cannot compel anyone to give them access to the flow. Congress might refuse to pass legislation requiring PSROs to share data with rate setters and no other federal institution could give rate setters that authority. The Secretary of HEW, for example, may not include rate setters in the PSRO review system - and no court could hold that failure to be an abuse of discretion. A court may refuse to grant rate setters' demands under the FIA, finding either that PSROs are not federal agencies, that the PSRO statute bars disclosure, or that the personal privacy of doctors transcends the importance of rate setting. The appellate courts almost certainly would uphold that finding.

The answer lies ultimately in the political process. If rate setting attains public importance, influential allies, and organized support, its route to PSRO data will lose much of its bumpiness,

some of its roadblocks, and a few of its potholes. Information provides power; control of the flow of information - a way to allocate power - becomes itself a source of power. The final question must be political: who can push whom hard enough to direct the flow of PSRO information?

II. DISCLOSURE BY REGULATION

Two sections of the statute that created PSROs require that the Secretary of HEW issue regulations concerning PSRO disclosure.[1] One section governs the regulations pertaining to the exchange of data between agencies; the other section governs all other disclosure, including public disclosure. The statute established criminal penalties for anyone who discloses information whose disclosure is not permitted by the statute.

The Secretary of HEW has promulgated a tentative version of the regulations,[2] which will delineate the circumstances under which PSROs may disclose data they have gathered to perform their legally mandated functions. The regulations, of course, will be legally binding.

Although the statutory language is expansive enough to permit the Secretary to promulgate wide-open disclosure regulations, the statute emphasizes inter-agency disclosure, rather than public disclosure. Government agencies presumably have more specific and legitimate needs for PSRO data, and the disclosure regulations will permit them greater access. Moreover, the Secretary always can provide for public disclosure after inter-agency transfer, but he cannot retract data once the public has seen them.

A. Who Has Access: The "PSRO Review System"

1. Who Has Access in General

The PSRO statute forbids all disclosure of information gathered by PSROs, except

> (1) "to the extent that may be necessary to carry out out the purposes of the part, or (2) in such cases and under such circumstances as the Secretary shall by regulation provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care."[3]

A PSRO, therefore, can disclose only that information which the PSRO law and regulations permit to be disclosed; Congress heavily circumscribed permissible PSRO disclosure.

The Statute contains several provision requiring the disclosure of PSRO information.[4] Most importantly for rate-setters, the statute directs the Secretary of HEW to provide for the interchange of data

> "consistent with economical, efficient, coordinated and comprehensive implementation of the part...between and among -
> (a)(1) agencies and organizations which are parties to agreements entered into pursuant to section 1816, (2) carriers which are parties to contracts entered into pursuant to Section 1842, and (3) any other public or private agency (other than a Professional Standards Review Organization) having review or contract functions or proved relevant data-gathering procedures and experience, and
> (b) Professional Standards Review Organizations, as may be necessary or appropriate for the effective administration of Title XVIII, or state plans approved under the Act."[5]

Congress thus indicated its judgment that disclosure to those agencies is necessary to carry out the "purposes of the PSRO law."

HEW will implement this statute by promulgating disclosure regulations. The regulations define which agencies shall share PSRO data,[6] and precisely what data they will share.[7] The regulations also specify procedures that patients must use to see their own records,[8] the PSRO employees that may see PSRO records,[9] and the extent to which a PSRO will disclose its own deliberations and findings outside itself.[10]

2. The "PSRO Review System" Defined

Most importantly, though, the proposed regulations define a "PSRO review system" which will have access to PSRO data and records.[11] Each component of the PSRO review system will have access to PSRO data "necessary to carry out its functions within the system."[12] Agencies that fall outside the definition of the "PSRO review system" will see only non-privileged PSRO information.[13]

HEW has defined the "PSRO review system" narrowly, reflecting its understanding of the statutory provision and corresponding legislative history concerning the inter-agency transfer to data. HEW apparently relies heavily on the statutory language that permits data exchange as "may be necessary or appropriate for the effective administration of Title 18 or state plans approved under this Act."[14] HEW looks also to the legislative history of the PSRO law. The Senate Report that accompanied the PSRO amendment[15] states:

"It is expected that the Secretary will develop necessary procedures for coordination between Medicaid agencies, Medicare carriers and intermediaries and the PSROs. To the extent that profiles are presently maintained by state agencies, carriers and intermediaries, these would be made available to PSROs."[16]

HEW interprets the PSRO statute and legislative history as requiring that PSROs share data with Medicare carriers and intermediaries,[17] data processors,[18] Medicaid agencies, and a few other state agencies.[19] The proposed regulations generally define the "PSRO review system" as:

"a system comprised of the PSRO and all supporting components which assist the PSRO in the review process or are furnished PSRO data for administrative purposes under Titles 18, 19, or 5 of the Social Security Act."[20]

Rate setters will be part of the "PSRO review system" only if 1) they have statutory or data-sharing authority under Titles 5, 18 or 19 of the Social Security Act, 2) they use PSRO data for "administrative purposes" under those titles, and 3) their use of the data would be consistent with the "effective, efficient, coordinated and comprehensive implementation" of the PSRO law.[21]

(a) Statutory Authority

No provision of the PSRO statute specifically limits the agencies that share PSRO data to those organized under Titles

5, 18 or 19.* PSROs must review the care of anyone provided services for which the Social Security Act might direct payment.[22] Since Titles 5, 18 and 19 alone provide for reimbursement for medical services under the Social Security Act, PSROs only concern themselves with - and provide data to - agencies organized under those titles.

If Congress were to add new titles to the Social Security Actk PSROs would review the care provided under those Titles, and would share data with agencies that the new Titles created. Rate-setters could fit into the "PSRO review system", then, if they were created by the addition of a new title to the Social Security Act.

If rate setters lack new Titles, they must rely on the old ones (5, 18,19) as their statutory authority. The PSRO statute requires the interchange of data among agencies organized under those titles[23] but permits other PSRO disclosure only in special circumstances.[24]

The statutory basis for rate setting thus becomes crucial here, while the importance of their organiztional structure recedes.

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*Title 5 authorizes expenditures on maternal and child health care; Title 18 authorizes expenditures on elderly people (Medicare); Title 19 authorizes expenditures for low-income people (Medicaid).

The proposed regulations would permit agencies to share PSRO data only if they have Titles 5, 18 or 19 as their statutory authority, or if the agencies already receive data from the Social Security Administration under those Titles. Some state agencies and Blue Cross Plans already set Title 18 and 19 rates; those agencies and plans could receive PSRO data. Agencies that set rates for Title 5 also could receive PSRO data. But rate setters with federal authority outside the Social Security Act (the Interstate Commerce Commission, for example) and state rate setters that do not now get data from Social Security Administration would not satisfy this requirement of the proposed regulations. Under the proposed regulations, then, the statutory basis for rate setting is more important than the organizational form that rate setting takes.

(b) "Administrative" Purposes

Even if rate setters have authority derived from the Social Security Act, they still must use PSRO data for "administrative purposes." The emphasis on "administration" tracks the language of the PSRO statute, which permits inter-agency data transfer to promote the "effective administration of Medicare and other plans under the Social Security Act."[25]

HEW argues that "administration" includes only basic clerical tasks, such as claims processing or eligibility determination, that other agencies perform to implement the Medicare, Medicaid, and Maternal and Child Health programs.[26] Agencies do not have "administration" functions simply because their performance of their particular tasks would be facilitated if they could use Medicare -- or PSRO -- data.

Thus, data processors, but not planning agencies or rate setters, could share PSRO data.[27]

The PSRO statute, however, suggests that the "administration" of Medicare requires the interchange of data between PSROs and any agency "having review or control function."[28] Congress has determined that such agencies should share PSRO data. Indeed, Congress did not require that the agencies be set up under Titles 5, 18 or 19; it only demanded that they promote the effective administration of plans under the Social Security Act.[29]

Rate setting bodies should have "review or control" functions. Commissions that set rates prospectively will have "control" functions,as their approval of hospital budgets or rates will greatly influence the care that a hosptial provides. Indeed, it is hard to imagine an agency's having greater control over a hospital than the power to set future rates or budgets.

Rate setters, then, should impinge on the administration of the Social Security Act through their review or control of hospital rates. They also must promote the "effective administration" of the Act before they can get PSRO data. One would hope they would. Rate setting bodies will help administer the Social Security Act by performing one of the central tasks that Act mandates: determining reasonable costs. Rate setters, if they perform their job well, should promote the "effective administration"of the Social Security Act.

(c) Implementation of the PSRO Law

Rate setters that set rates prospectively, then will have "control functions", and will promote the effective administration of the Social Security Act. But PSROs can furnish them data only as is "consistent with the economical, efficient, coordinated, and comprehensive implementation of this part."[30]

HEW will argue that wider disclosure than they have provided would undermine the effectiveness of the PSRO program.[31] The viability of the peer review mechanism, they argue, depends on the willingness of providers and physicians to provide information to the PSRO, and the continuing willingness of physicians to participate as reviewers of the care provided by other physicians. Disclosure of PSRO information, HEW continues, would dry up the sources of information and manpower for PSROs: no one would tell PSROs anything, and there would be no one there to listen anyway. There would be no implementation of this part, they conclude; no one will give PSROs a chance.

Providers and physicians, however, must provide information to PSROs, for no one will receive Medicare or Medicaid reimbursement unless the PSRO approves the claim.[32] Providers and physicians can choose not to give PSROs any information; in so doing, they also choose not to participate in the Medicare or Medicaid programs. PSRO disclosure may make doctors and hospitals disgruntled, but it will not make them silent - unless they would forego Medicare and Medicaid reimbursement.[33]

Nor would one expect doctors to forego participation in the PSRO program merely because they disliked PSRO disclosure policies. The PSRO statute explicitly permits the Secretary of HEW to designate a group of non-doctors as the local PSRO in an area, if he feels that the local physician group

has not effectively performed its PSRO tasks, and if he feels that the new, non-doctor, group will be competent.[33a] Nor would doctors elicit much public support for their refusal to participate in a program aimed at cutting costs and insuring the quality of care, especially if the program was working well without physicians' objections in other areas. Physicians might refuse to participate in PSROs - but that is probably unlikely and almost certainly ill-advised.

PSRO disclosure to rate setters, moreover, should not disrupt the process of PSRO deliberations. Rate setters probably will request PSRO data annually, or perhaps quarterly; the satisfaction of annual requests for data should not damage the normal processing of PSROs. Disclosure to rate setters, then, will be consistent with the economical and efficient implementation of the PSRO legislation.

Disclosure to rate setters would not undermine the implementation of the PSRO law; it would not shut off the flow of information to PSROs, nor would it disrupt the internal processing of the PSROs. Indeed, if rate setters could not get PSRO data, they might have to set rates without any measure of the intensity of services that hospitals provide. The lack of coordination between rate setting and quality review might introduce a new source of inefficiency into the administration of the Social Security Act; it might even torpedo the implementation of the PSRO statute. PSRO disclosure, a rate setter then could argue, would be "consistent with", even enhance, the effective implementation of the PSRO statute. Rate setters, therefore, should have access to PSRO data.

HEW finally would argue that Congress intended PSROs to serve as peer review mechanisms, not as information clearinghouses.[34] Congress

chose not to permit liberal disclosure when it wrote the PSRO statute; the broad purposes, stated in the first section of the bill, do not include anything suggesting disclosure to rate setters.

Rate setters should argue that Congress' work resembles architecture more than carpentry. Congress only provides the broad outlines of the structure that will eventually exist; the agencies that implement the law really serve as the carpenters, who fill out the structure according to plan. The plan - as set forth in the section on statutory purposes** - is consistent with liberal disclosure, even if it does not mandate such disclosure. Congress' silence on PSRO disclosure to rate setters, does not necessarily reflect its deliberate choice; it may only have left the decision to HEW.

3. Summary

HEW, then, should include rate setting commissions in the "PSRO review system", but only if they have Titles 5, 18 or 19 as their statutory authority. The PSRO statute would permit any agency that promoted the effective administration of the Social Security Act to be in the system, provided the agency met certain other tests. The regulations, however, define the system more narrowly.

Rate setters will have "review or control" functions, which will aid in the administration of the Social Security Act. Moreover, they will not disrupt normal PSRO processing or information flow if they get PSRO data - and their failure to get PSRO may be disruptive, and hence undermine the implementation of the PSRO law. PSROs, therefore, should disclose their data to rate setters.

B. What Data Are Available: "Privileged Information"

1. General Availability of Data

The proposed regulations forbid PSROs and their agents from collecting

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** See pages 46-49, infra, on the "purposes" of the PSRO law, and the consistency of those purposes with disclosure to rate setters.

data other than "that necessary for the purposes of PSRO review and/or evaluation."[35] "Evaluation" pertains only to the assessment of the effectiveness of PSROs and their impact on the provision of medical care.[36] "Review" pertains to the duties and functions that PSROs perform.[37] Therefore, PSROs or other components of the "PSRO review system" may gather only that data necessary for the PSRO to fulfill its statutory duties, and that necessary to evaluate the effectiveness and impact of PSRO review. PSRO data, therefore, might not contain all the information that rate setters need.

Rate setters' access to PSRO data depends fundamentally on whether they are part of the "PSRO review system": Components of that system have access to "privileged" information, if it is "necessary to carry out ... [their] functions within the system."[38] However, rate setting bodies will be able to get non-privileged information simply by requesting it and by paying a fee to cover the expenses of copying the requested information.[39] The PSRO system even will generate non-privileged information for research purposes, if rate setters request it and pay for expenses of generating it.[40]

2. "Privileged" Information

The definition of "privileged information" then, is crucial, for rate setters outside the "PSRO review system" will be unable to obtain any information that is privileged. The proposed regulations define "privileged information" as

> "medical data and information identifiable to an individual patient, data and information indicating patterns of health care paratices identifiable to individual health care pratitioners, records of PSRO determinations identifiable to individual practitioners and data and information collected and/or generated for MCE studies as defined in department regulations guidelines."[41]

"Privileged" information does not travel far. The proposed regulations carefully limit the circumstances under which PSROs may disclose privileged information. PSRO deliberations, for example, cannot be disclosed to anyone outside the PSRO[42] - even in response to a subpoena.[43] Federal or state agencies that monitor PSRO performance may not transmit privileged PSRO data outside its physical location.[44] None of the guidelines permits rate setters to see privileged PSRO information - unless they are part of the "PSRO review system."

(a) "Identifiability"

The crucial part of the definition of "privileged" information is the definition of "identifiability". Another regulation defines identifiable data as "data collected, generated or aggregated on a particular individual which identifies that individual either explictly explicitly or by implication."[45] HEW added the words "on a particular individual" to emphasize that the regulations permit disclosure of information that has been collected or tabulated about groups of individuals (and thus no particular individual).[46] To be sure, HEW could have phrased the regulations more felicitously, to indicate that "identifiable" information was information whose unit of observation was a particular individual.[47]

Three other problems with the definition of "identifiable" remain. The definition speaks of identifying an individual "explicitly or by implication." How strong an "implication" must the data have? Is a mere hint enough? Must the implication be almost explicit? How clearly should the data indicate the identity of the person whom they describe?

A related problem is one that might be called the "small number problem". If, for example, a hospital has one brain surgeon, then any information about brain surgery will "identify" that person - even though the PSRO did not intend to describe him, but only to describe brain surgery in the hospital. The proposed regulations apparently would prohibit the disclosure of information about a department that had only one physician, regardless of whether anyone outside the hospital knew that the department had only one doctor. That information, the regulations suggest, would be "identifiable" to the doctor, even though no one in the surrounding community actually could identify him.

The regulations present a third problem: how much outside information will render information "identifiable" to a particular individual? Suppose a hospital has two brain surgeons, each with his own technique, reflecting his own education and training. If a PSRO gathered information about all the brain surgeries in the hospital, and classified the information by technique, would the information identify each of the surgeons "by implication"? How many people would have to know the particular techniques each surgeon used before the regulations call information about the techniques "identifiable"? Anyone? The hospital staff? The medical community? How many people must know, and how much must they know? Many people might know that the two surgeons used different techniques, but would not know who used which technique. Would disclosure of information about surgery, clasified by technique, then be "identifiable"?

HEW plans to issue guidelines that will further explain the regulations.[48] HEW plans to resolve the "outside information" problem by defining "identifiable" in terms of the number of people within the hospital who might fit the description. The PSRO thus will be less likely to release the information as the number of people who might fit the description dwindles. This formulation, however, leaves unclear just how many people must fit within the description before the PSRO will release the information. Furthermore, the guideline leaves unclear just how closely a person must fit within the description before it identifies him. All physicians at a particular hospital, for example, fit within one element of a description of another physician at that hospital: they all are physicians associated with the hospital. Few physicians will fit within a description of a neurosurgeon who graduated from Tufts Medical School, works only during the morning, and sews only with his left hand. By manipulating the manner in which it determines whether an individual fits within a particular description, HEW - and thus a PSRO - can control the outflow of PSRO information.

(b) Other "Privileged" Information

HEW, of course, might leave the decision up to each PSRO. Each PSRO then would have tremendous discretion in deciding what information it would release. Rate setters might get information from one PSRO in a state while another PSRO in the same state denied them the same kind of information - and each decision would rest within the permissible range of discretion of the PSRO. It would

be difficult and expensive to appeal to higher authorities within the PSRO system, to reverse this decision; rate setters would have no guarantee of success.

Rate setters, then, could not get PSRO information that "identified" individual patient or physicians, nor any data collected for Medical Care Evaluation (MCE) studies. The PSRO Program Manual,[49] which HEW has issued to guide PSROs through their legal requirements, defines MCEs as retrospective studies that assess the quality and nature of the utilization of health care services.[50] MCEs will require information "related to the care provided by a number of practitioners to a number of patients."[50]

Data gathered for MCEs, then, probably will not be "identifiable" as the regulations define that term. However, data gathered for MCEs may include any other information that PSROs will gather, for MCEs will concern groups of doctors. Information about particular individuals, then, would be "identifiable," and thus privileged; information about groups of patients or doctors would be for MCEs, and thus privileged. All PSRO information then would be "privileged": data about individuals would be "identifiable", and data about groups would be "gathered for MCEs." A PSRO could put any data about groups into the latter category, and would disclose nothing. A complete refusal to disclose would violate the spirit of the PSRO law, and conflict with HEW policy on the matter. The regulations in their present version nonetheless permit it.

HEW hopes to permit the release of some PSRO data by limiting the quantity of data that can fit into the MCE part of the definition of "privileged". It probably will define MCE data as only that data

gathered specifically for the purposes of MCE data, and not any data that describes groups of patients or physicians.[52]*

PSROs, though, will only collect data for four purposes: 1) concurrent certification of the admission of patients; 2) review of patient's continued stay; 3) MCEs; and 4) profiles of physicians, patients, and providers.[53] Data on admission certification and continued stay review, however, necessarily involve the identification of individual patients and physicians, and so will not be diclosable. MCE data cannot be disclosed. Physician and patient profiles necessarily identify individuals, and so presumably cannot be disclosed. These leave only provider profiles, which will describe the various services (surgical, obstetrical, and so on) in a hospital. Presumably, a PSRO may disclose provider profiles, but only if they do not identify physicians or patients, and do not rely on data gathered for MCE studies.

The regulations could avoid this problem by permitting PSROs to release information whose identifying details had been deleted.** The information would no longer identify individuals, although it once did. This procedure would permit rate setters to obtain statistical data on hospital casemix, demographic data on the patients that the hospital served, and possibly even some crude measure of the quality of care. Rate setters could use these data without being able to identify the individual patients or doctors, and without relying on MCE data.

*The tentative version of the guidelines on PSRO disclosure regulations defines MCE studies this way.

**The tentative guidelines permit this procedure, which conforms with the spirit of the PSRO law.

The proposed regulations, though, do not expressly permit these procedures, although the spirit of the regulations does. A PSRO reluctant to disclose might argue that the Secretary promulgated the regulations as part of his power to create exceptions to the general policy of non-disclosure by PSROs. If the regulations do not explicitly permit disclosure after the deletion of details, then the PSRO statute forbids it. Indeed, a physician or provider that wanted to block disclosure could advance this argument to the PSRO. The PSRO would have to choose between 1) violating the spirit of the regulations, and withholding data that Congress intended to be released, and 2) adhering to the spirit of the regulations, releasing the data, and risking the imposition of criminal penalties for illegal release of PSRO information. A PSRO probably would withhold the data.

HEW could avoid this by explicitly permitting a procedure whereby PSROs would delete identifying details. Information that was privileged when collected need not remain so forever. If no one can identify particular individuals by using the released data, the substantive command of the PSRO statute will have been satisfied.

C. SUMMARY AND CONCLUSIONS

PSROs probably will collect most of the kinds of patient related data that rate setters now have the capability of using in their decision making. It seems likely that rate setting bodies may be

able to secure the kinds of statistical profiles they require to show differences among hospitals in respect to hospital service areas, patient casemix, utilization and the demographic characteristics of patients. However, there are possibly obstacles to the securing of even such profiles: should they wish occasionally to use privileged information, the obstacles would be much greater.

Rate setters will be able to use privileged PSRO data only if they are part of the "PSRO review system" and only if they need the data to perform their functions within the PSRO review system. If rate setters do not fit into that system, they will at best, see only non-privileged information. Non-privileged information, as defined by the proposed regulations, cannot identify any individual doctor or patient, either "explicitly or by implication." Moreover, the data cannot have been that generated for Medical Care Evaluation Studies. In the future it is possible that rate setters and hospitals may want certain types of data that might be deemed "privileged".

In any event, if rate setters are not defined as part of the review system, individual PSROs will have tremendous discretion in deciding what information to disclose - unless HEW tightens its own command of the disclosure regulations. Rate setters can join the "PSRO review system" only if they have rate setting or data sharing powers authorized by Titles 5, 18, or 19 or the Social Security Act. They must show that they

- are an agency having "review or control" functions;
- will enhance the administration of the Social Security Act by their use of PSRO data;
- will use the data in a manner consistent with the effective implementation of the PSRO statute.

Rate setters for Social Security Act Titles should be able to make this argument persuasively, since by determining reimbursement prospectively for hospitals give care to Social Security Act beneficiaries they will be agencies with 'review and control functions'. They should enhance the administration of the Social Security Act by restraining hospital cost inflation. Demonstrating that their use of data would not interfere with the effective implementation of the PSRO statute would be the most difficult task, since widespread disclosure of privileged (and perhaps even non-privileged) information would undoubtedly provoke political opposition to the program which would indeed prevent its effective implementation.[54]

Finally, rate setting bodies would have to convince the Secretary of HEW that they meet the above three part test imposed on them, for Congress has rested the authority in him. Rate setters probably would have a difficult time persuading a court to reverse the Secretary.

A specific law would avoid many of the potential legal pitfalls that await rate setters seeking PSRO data. A Congressional determination that rate setting will promote the effective administration of the Social Security Act would require PSROs to share data with rate setters. Rate setters then would avoid reliance on the discretion of particular PSROs or HEW. Congress did this in the 1974 Health Planning Act,[55] and so could easily require PSROs to share data with rate setters.

III. DISCLOSURE BY STATUTE: THE FREEDOM OF INFORMATION ACT

The PSRO disclosure regulations may prevent rate-setters from getting any "privileged" information. Rate-setters then will have to resort to a general disclosure statute. The Federal Freedom of Information Act (FIA)[56] could prove useful - but rate-setters can use the FIA only if they are not federal agencies, and if PSROs are federal agencies. If PSROs are not federal agencies, rate-setters will be able to use the FIA to get only the PSRO reports or data that HEW has already received from PSROs - which would greatly limit the usefulness of the FIA.

The FIA, the federal disclosure act, replaced Section 3, the public information provision of the Administrative Procedure Act. The Senate Report accompanying the FIA noted that Section 3 had become a public silence statute, as federal bureaucrats withheld information to avoid examination, embarassment, or minor inconvenience.[57]

Angered by what it thought was the bureaucrats' self-serving refusal to divulge "public" information, Congress passed the FIA in 1966. The Act, one proponent urged, would "shred the paper curtain of bureaucracy that covers up public mismanagement with public misinformation, and secret sins with secret silence."[58] The sponsors of the Act argued that it would help create an informed electorate, which was the bedrock of American democracy.[59] The bill passed both Houses without a dissenting vote, and took effect a year later.[60]

Subsequent events in the executive branch undermined Congressional expectations. Critics charged that agencies gave preferential access to special interest groups, and that agency officials displayed considerable ingenuity in perfecting schemes to avoid the substantive policies of the FIA.[61] Agencies became adept at delay, evasion, and avoidance.*

Congress thus amended the FIA in 1974, by clarifying some of the more opaque provisions, limiting the permissable period that an agency could delay, and strengthening the jurisdiction of the federal courts. The amended FIA took effect in February 1975.

The amended FIA applies to Federal agencies. It directs them to publish in the Federal Register the procedures that people must follow to obtain agency records and decisions.[62] It also directs agencies to maintain and make available indices to agency decisions, rules, and policies, and to allow the public to inspect and copy those decisions and rules.[63] Moreover, the agency must make available to "any person" any records that are "reasonably described" in a procedurally-correct request.[64] The federal courts have jurisdiction to compel agency disclosure, and the agency must bear the burden of proving adequate reasons for non-disclosure.[65]

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* Some agencies, of course, had nobler motives - the realization, for example, that full public disclosure of some classes of information would diminish respondents' willingness to provide the information in the first place. FIA reformers, uncharitably disposed toward all agencies because some agencies acted duplicitously, sometimes overlooked the nobler motives.

However, the FIA does not apply to matters that fall within 9 specified exceptions.[66]

The FIA does not allow one federal agency to obtain the records of another one. Section 552(a) of the Administrative Procedure Act (APA) requires that an agency disclose its records to "any person." Section 551 of the APA defines "person" for the FIA as "an individual, partner, corporation, association, or public or private organization other than an agency."[67] Although the definition of "agency" is subject to much debate (see below) an entity must have federal authority, at the very least, before it is an "agency". An entity with state statutory authority probably would not be an "agency". A rate-setter, then, cannot be a federal agency if it is to use the FIA to get PSRO data.

A. Does the FIA apply to PSROs?

1. Statutory Definition of "Agency"

The FIA applies to PSROs only if they are "agencies" within the meaning of Section e of the amended Act. Section e provides that:

> "For purposes of this section, the term 'agency' as defined in Section 551(1) of this title, includes any executive department, military department, government corporation, government-controlled corporation, or other establishment in the executive branch of the government, or any independent regulatory agency."[68]

A PSRO does not fit the definition of an "executive department," nor that of a "military department". Yet a PSRO might be any of the other authorities that the FIA definition includes, except an "independent regulatory agency", whose members the President appoints.

2. Legislative History

The Congressional reports that accompanied the 1974 FIA amendments through Congress provide slightly more guidance. The House report spoke

of extending FIA coverage to organizations that "perform governmental functions and control information of interest to the public."[69] The Conference Report, which set out the agreement of Senate and House conferees who met to reconcile the two versions of the amendments they passed, indicates that the Conferees "...do not intend to include corporations which receive appropriated funds but are neither chartered by the Federal government nor controlled by it..."[70]

PSROs will receive government funds,[71] but the Federal Government will not charter them.[72] A PSRO will be an 'agency' then, only if the Government controls it (to use the Conference test) or if a PSRO performs "government functions" (House Test).[73]

HEW argues that PSROs will not perform the functions of the government, only the function of the medical profession. PSROs serve only as mechanisms for peer review, it argues; it does not perform functions that the Secretary would perform if PSROs did not. The government financing, the argument goes, only helps those who review themselves.[74]

Congress, however, mandated the establishment of PSROs to review the care that Medicare and Medicaid patients get, because it felt that many of the services provided to those patients "probably are not medically necessary."[75] It is the government's function to audit the payments it makes under Medicare and Medicaid, because those programs use federal funds. Moreover, if PSROs did not review these services, the government almost certainly would, reflecting its concern over rising Medicare costs, and the possible dangers that overutilization poses for the health of the elderly.[76] The Senate Report that accompanied the PSRO legislation states:

> "There is no question, however, that the Government has a responsibility to establish mechanisms capable of assuring utilization review."77

PSROs, then, have taken a "responsibility" of the Government, by serving as peer review mechanisms. Indeed, had Congress intended only to help PSROs review the medical profession, it would not have limited the scope of their permissible review to services for which payment might be made under the Social Security Act;[78] nor would Congress have ordered the Secretary of HEW to choose a non-medical group to be a PSRO if the local medical society proved unwilling or unable.[79] PSROs really will perform auditing and review jobs on the behalf of the government, and thus meet the House test: PSROs will perform government functions.

Even if PSROs perform governmental functions, HEW argues, the government does not exercise enough control over them to bring them within the FIA. PSROs are private, independent organizations, concerned with their own business, the argument goes, and the government merely aids them by providing money and technical assistance. PSROs essentially will run their own organizations. For purposes of the FIA, PSROs will be no different from any other private contractor that the government hires[80] - like Lockheed, for example. Although the government exercises more control over PSROs than over Lockheed, both organizations are merely private contractors and thus are indistinguishable under the FIA.

PSROs, though, are not like Lockheed. Much of Lockheed's business comes from outside the government; PSROs exist only to perform a government function. PSROs, moreover, exist only because a federal law explicitly created them. Further, the government exercises far more control over PSROs than it does over Lockheed, and almost certainly enough control for FIA purposes. Federal law or Federal officials determine who can be a PSRO, the functions

and duties of a PSRO, the responsibility of a PSRO, the procedures a PSRO must follow, and the compensation it will receive. Each PSRO has little choice or latitude in the manner in which it will perform its functions.

Federal law essentially determines who shall be a PSRO, and what a PSRO must do. Each organization seeking to be a PSRO must comply with specified conditions concerning its membership.[81] PSROs must review the health care given to Medicare and Medicaid patients in their areas;[82] PSROs must review admission decisions for all such patients in their areas.[83] PSROs must maintain physician provider, and patient profiles.[84] PSROs must develop norms for care, treatment, and diagnosis.[85]

PSROs also must comply with the procedural requirements that the law imposes.[86] They must publish their case criteria. They must notify any practitioner or provider if they make a determination adverse to him or it.[87] A PSRO must give practitioners and providers a chance to rebut an adverse report[88] and provides an opportunity for the practitioner or provider to appeal.[89]

The federal government thus controls what a PSRO will do, and in some cases, how it will do it. The federal government exercises further control through the Secretary of HEW, who is to maintain watch on PSROs. The Secretary determines the area a PSRO will serve[90] and evaluates the qualifications of a PSRO.[91] No PSRO comes into existence, remains in existence, or performs any functions without the approval of the Secretary.[92]

More importantly, a PSRO must comply with any regulations that the Secretary promulgates, and must fulfill any duties or functions that the Secretary thinks it should fulfill.[93] Only the Secretary may permit a PSRO to take on other duties, and it may not take on

new duties without his permission.[94] A PSRO must collect data, as but only as, the Secretary determines is necessary to implement the PSRO legislation.[95]

PSROs may freely develop the particular substantive criteria and norms that the statute mandates, but they must do so within the strict confines of that law and the Secretary's regulations. PSROs have substantially less freedom to run their organization and to perform their services than does a federal contractor - Lockheed, for example. PSROs should meet the test that the Conference Report proposes: governmental control of corporate functions.

3. Case Law

A PSRO should be an 'agency' under the amended FIA, then, if the legislative history is any guide. But a court might be hesitant to rest its decision on the meager guidance of the legislative history. Caught between the Scylla of finding all meaning in one sentence and the Charybdis of disregarding Congress completely, a court would turn to the case law. The amended FIA took effect in February, 1975, so no reported cases have construed the new definition of agency. A court then would look to the cases that illuminated the pre-amendement definition of 'agency' that applied to the FIA.

PSROs probably were 'agencies' under the case law concerning the FIA before it was amended.

Courts have defined agencies as government organizations that have "decisional authority." The court used that standard in an important recent case: Washington Research Project v. HEW.[96] The Appellate Court, reversing the Distrcit Court, held that NIMH "initial review groups"

(IRGs) are not agencies within the meaning of the FIA, because they have no "authority in law to make decisions."[97] The National Advisory Mental Health Council only listened to IRG recommendations, but was not bound by them. "The fact that the NAMHC may be greatly influenced by the IRG's expert view does not make the IRG an agency."[98]

Washington Research is important because IRGs closely resemble PSROs in several ways. IRGs perform peer review of non-governmental practices in a technical area; only non-governmental individuals may sit on the panel. Moreover, their recommendations, which go to officials in the government hierarchy, are effectively equivalent to decisions; the NAMHC relies almost exclusively on IRG reports in allocating grant money. PSROs also have non-governmental persons engaging in peer review of a non-governmental service that requires technical expertise. PSRO recommendations, moreover, will go the Secretary of HEW, who will carry out the recommendations unless the hospital successfully appeals.

In legal terms, however, IRGs differ from PSROs in at least one crucial respect: IRGs lack any statutory authority. As the court noted in Washington Research, supra, the governmental official never need follow IRG recommendations; they consider the recommendations to be only advice - expert advice, admittedly, but still only advice.

The Secretary of HEW, by contrast, must follow PSRO recommendations. He can reimburse a provider only if the local PSRO approves the claim.[99] The provider may appeal,[100] but if it does not, the PSRO decision is binding, and the provider gets no reimbursement.[101] The PSRO makes decisions; IRGs make only recommendations. PSROs thus should satisfy the Washington Research definition of an agency.

Other cases have insisted that an agency is "any administrative unit with substantial independent authority in the exercise of specific functions."[102] A PSRO does have authority in the exercise of the specific functions it performs, but it is not clear how much independent authority equals "substantial" independent authority. An agency need not have final authority to have substantial independent authority.[103]

Some courts have found executive entitites to be "agencies" even though the entities lacked "decisional authority".[104] However, the court applies this standard only to agencies created by executive order - i.e., ones that lack explicit Congressional approval. Courts apply a more inclusive definition of 'agency' to executively-created agencies (and thus apply the FIA to agencies that wouldn't otherwise have to comply with it) to safeguard the balance of federal power. Since Congress cannot insist that executively-created agencies have wide-open disclosure laws, nor that those agencies comply with a general disclosure statute, the courts watch those agencies more carefully.

When Congress has a chance to create (or at least acquiesce in) the creation of an agency, however, the courts apply a less-inclusive standard to define "agencies" and require that the governmental entity exercise more authority before it is an "agency". The courts impute significance to Congress's failure to require disclosure of the agency, and thus apply a less-embracing definition of agency. The courts insist only that Congress call an 'agency' anything it creates as an 'agency'! Thus, if the government entity - like a PSRO - exercises substantial authority, it will be an "agency".

In Soucie, supra, for example, the court emphasized that Congress has acquiesced in the executive reorganization plan that created the Office of Science and Technology (OST). OST took on duties that Congress had delegated previously to the National Science Foundation (NSF). Congress could have insisted that OST adopt very liberal disclosure rules, but did not. The courts, therefore, insisted that OST exercise substantial independent authority, before it would be termed an agency. Since OST did make decisions and allocate resources where NSF once did, the court held that OST was an agency.[105]

PSROs, as noted above, were also created by statute. Courts probably will require that they exercise "substantial independent authority" before the FIA will apply to them. This approach, exemplified by Soucie, supra, follows the approach of Professor James Freedman, whom the Soucie court cites as an authority.[106] Freedman states the test to be whether the authority has "substantial powers to act with respect to individuals."[107]

4. Summary

It remains unclear whether PSROs would be considered 'agencies' under the pre-amendment FIA. PSROs do exercise 'decisional authority,' and direct the flow of billions of dollars of Medicare and Medicaid reimbursement. They may wield great power over hospitals and physicians by setting medical norms. Will this be "substantial" independent authority?

The amended FIA presents further problems. Since a government entity was an 'agency' under the old FIA if it exercised "substantial" independent authority, what did Congress mean when it said it sought to expand the coverage of the FIA? It might have meant only to codify the case law that

Soucie represents. But it might also have intended to extend the coverage of the FIA to entities that contract with the government to perform government functions under government direction.

In either case, PSROs probably should fall under the FIA definition of 'agency'. PSROs will perform a government function: the review of care given to Medicare and Medicaid patients. They will perform it under substantial federal control, through statutes and regulations.

PSROs nonetheless will retain substantial authority within the constraints imposed by Congress and HEW. PSROs will decide whether providers receive reimbursement for the services they gave to Medicare and Medicaid patients - decisions that will allocate billions of federal dollars. It is hard to imagine any authority that is more "substantial."

The same analysis, of course, will apply to rate-setters. If a federal statute creates the rate-setting authority, and a court finds that rate-setters exercise "substantial independent authority", then the rate-setting commission will be an 'agency' under the FIA, and will be unable to use the FIA to get information from PSROs. A court almost certainly would find that a commission that set rates under Titles 5, 18 and 19 would exercise "substantial independent authority" - and so would have been an 'agency' under the FIA even before it was amended. If rate-setters determined rates under a direct grant of authority from the Social Security Act, most courts would find that rate-setters performed a government function - and so should be an 'agency' under the newly amended FIA. If rate-setters had federal authority and a statutory mandate to set Medicare and Medicaid rates, they would find it very difficult to argue that PSROs were agencies but that rate-setters were not agencies.

Rate-setters will have less trouble using the FIA if they have state statutory authority. The rate-setting commission clearly would not be a federal agency, and still could set Medicare and Medicaid rates if they had a waiver from the Social Security Administration to do so. Indeed, a state might deliberately write its rate-setting statute to require that rate-setters cooperate with the Social Security Administration. A state statutory foundation, closely linked with Medicare and Medicaid rate determinations or federal waivers would permit the rate-setters to use the FIA.

B. FIA REQUIREMENTS

If the courts find that PSROs are 'agencies' under the amended FIA, then the PSROs must comply with all the requirements of that statute. Specifically, if "any person" makes a request for PSRO records, the agency must "promptly" comply with that request. The request need only "reasonably describe" the records, and comport with the agency procedures for obtaining records.[108] The agency must publish the procedures in the Federal Register.[109]

Rate-setters should use the FIA because it requires agencies to respond to a request for records within 10 working days.[110] If the agency fails to comply, the person requesting the records may file a complaint in federal district court.[111] The agency must file its answer within 30 days,[112] and the court is to give the case precedence over all others on the docket, "except as to those the court considers of greater importance."[113]

Rate-setters that are not federal agencies, then, can use the FIA to provide a regular flow of information from PSROs. PSROs would have to respond "promptly" and would have to make available all their records - unless the records fell within one of the specific exemptions of the FIA.[114]

C. DO PSRO RECORDS FALL WITHIN ANY OF THE FIA EXEMPTIONS?

The FIA states that it "does not authorize withholding of information to limit the availability of records to the public, except as specifically stated in this section."[115] Section (b) states that the FIA does not apply to matters that fall within one of the nine enumerated exceptions to the Act. Moreover, "the policy of the Act requires that the disclosure requirement be construed broadly, the exemptions narrowly."[116] The exemptions do not require non-disclosure; they merely permit it.[117] An agency may disclose information that falls within one of the exceptions, but practical pressures combine bureaucratic conservatism to produce few cases where agencies willingly disclose records that the FIA indicates they may withold.[118]

A rate-setter would have to show that no FIA exemptions would apply. A PSRO almost certainly will not disclose data unless the law requires it since few PSROs would want to risk the criminal penalities that the statute imposes for illegal disclosure. If any FIA exemption blocked disclosure, then a PSRO would not disclose.

The FIA has 9 specific exemptions (see appendix II). Four of them may apply to the records that rate-setters seek.

- the exemption for matters whose disclosure is forbidden by statute, (#3);
- the exemption for confidential commercial information, (#4);
- the exemption for intra-agency memoranda, (#5);
- the exemption for files whose disclosure would constitute an invasion of privacy (#6)

1. Statutory Exemption

(b) "This section does not apply to matters that are -

...

(3) specifically exempted from disclosure by statute";

Concerned that they may have overridden other statutes that forbade disclosure, Congress wrote exemption 3 into the FIA. The PSRO statute contains a provision that bars most disclosure. Does it bar disclosure to rate setters?

(a) Is There a Statutory Bar?

The PSRO statute instructs PSROs that all data they gather

"shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall be regulations provide to assure adequate protection of the rights and interest of patients, health care practitioners, or providers of health care."[120]

The Secretary has proposed regulations governing the disclosure of PSRO data "necessary to carry out the purposes of this part." HEW has interpreted this provision to forbid all disclosure not necessary to "carry out PSRO responsibilities."[121] HEW argues that the "purpose" of the PSRO legislation is to establish a nation-wide system of mechanisms for peer review that would review the care Medicare and Medicaid patients receive.[122]

The "purposes of this part", though, are not simply to establish a network of PSROs.[123] Congress clearly stated the purposes of the PSRO statute in the 1st section of that law:

"in order to promote the effective, efficient, and economical delivery of health care services of proper quality for which payment may be made (in whole or in part) under this Act, and in recognition of the interests of patients, the public, practitioners and providers in improved health care services, it is the purpose of this part to assure, through the application of suitable procedures of professional standards review, that the services for which payment may be made under the Social Security Act will conform to appropriate professional standards for the provision of health care and that payment for such services will be made (1) only when, and to the extent, medically necessary..."[124]

The law seeks to "assure" that the care given to Medicare and Medicaid patients will be of adequate professional quality, and that the Social

Security Administration will not make reimbursement for unnecessary care, PSROs serve as instruments to achieve those purposes: it is "through the application" of PSRO review that the substantive ends of the Act will be achieved.

The legislative history supports this view. The Congressional report that accompanied the PSRO statute indicates Congress' concern with the rising costs of Medicare. This inflation has two causes, the report explains: the increase in unit price of the services that hospitals provide, and the vast increase in the amount of services provided.[125] The committee added:

> "...the economic impact of this over-utilization becomes extremely significant. Aside from the economic impact the committee is most concerned about the effect of over-utilization on the health of the aged and poor. Unnecessary hospitalization and unnecessary surgery are not consistent with proper health care."[126]

The Report[127] explains that utilization review (UR) mandated under Medicare had proved ineffective in limiting either rising cost or rising volume.[128] The committee noted that utilization review as then conducted was generally "of a token nature" and "more form than substance."[129] The committee believed that doctors could more effectively review the care given to Medicare and Medicaid patients if PSROs were established.[130]

PSROs, like the UR committees before them, seek to assure the hospitals will use their resources effectively. PSROs, though, are only devices, a "structure between Government and Medicine," as Senator Bennett, sponsor of the PSRO legislation, described it.[131] The Committee Report described the Bennett Amendment by saying:

> "The purpose of the amendment would be to assure the proper utilization of care and services provided in Medicare and Medicaid utilizing a formal professional mechanism..."[132]

PSROs, then, are "mechanisms."

A federal court, passing on the constitutionality of the PSRO legislation, wrote:

> "In order to avoid over utilization of health care services and to achieve more effective control over the costs of those services, Congress enacted the 'Professional Standards Review' legislation." 133

and:

> "the primary purpose of the Act is to control the rapidly rising costs of governmental health care systems." 134

HEW notwithstanding, then, the purposes of the PSRO law are clear: to limit overutilization of hospital services by Medicare and Medicaid patients, and to restrain the drain of funds from the Social Security Trust Fund. If disclosure of PSRO information to rate-setters would help achieve those purposes - "would be necessary to carry out the purposes of this part" - then the PSRO statute would permit that disclosure. No statutory bar to disclosure would exist, and the third FIA exemption would not apply.

Rate-setters, one would hope would seek the same purposes, even though they used different methods to attain them. If the Social Security Act provided the statutory basis for rate-setting, rate-setters would directly influence the reimbursement rates paid under Medicaid and Medicare. However, the rate-setting commission almost certainly would be an 'agency' under the FIA, and thus could not use that statute to get PSRO data.

Rate-setters could seek the same purposes less directly. A state might require that rate-setters determine rates in a manner that would promote the efficient use of hospital resouces by all patients, including Medicare and Medicaid patients. The state law might require rate-setters to coordinate their efforts with the Social Security Administration, or even to set rates in a way that helped to minimize Medicare and Medicaid

payments, and did not prompt misutilization of hospital resources by Medicare and Medicaid patients. Rate-setters, even though they had state statutory authority, still would try to promote effective use of Medicare and Medicaid. resources - which is the basic purpose of the PSRO law.

Congress, of course, might help persuade the states to write rate-setting laws that required the commissions to co-ordinate their rates with Medicare rates. Congress could offer the state considerable federal assistance, technical and financial, if the states would write such provisions into their rate-setting laws. Congress could create substantial <u>incentives</u> for states to frame their law that way,[135] but Congress could not direct the states to do so without creating a large risk that a court would rule that the "state" rate-setters really were a federal agency.

The 1974 Health Planning Act[136] might serve as an example of such federal legislation. The legislation established 'health systems agencies', which will evaluate the health of the population in a state region and will provide long and short range plans to improve the health of that population.[137] HSAs may not fit within the FIA definition of agency. HSAs must be a public regional planning body, a single unit of local government, or a nonprofit private corporation incorporated in the state it serves and not controlled by any other legal entity.[138] Neither the local government unit nor the regional planning body will be an 'agency' under the FIA. Arguably, the private non-profit planners will not be either, since the Federal government neither charters nor controls them. However, the planners might be an agency because they must approve or disapprove the use of federal funds,[139] and therefore may exercise 'substantial' independent authority.

The 1974 Planning Act may provide a good example for a possible federal rate-setting act - one that even might be part of the Social Security Act. Congress can avoid creating 'agencies' by carefully detailing the legal structure that any rate-setting commission would have to have. Congress might avoid any potential problems under the FIA by not giving rate-setters the power to approve or disapprove the disbursement of federal funds; rate-setters would determine state rates. Congress also would require rate-setters to restrain medical inflation, while maintaining the quality of care. Indeed, Congress required HSAs to pursue exactly those purposes[140] - which resemble very closely the purposes of the PSRO law. The PSRO statute then would not bar PSRO disclosure to rate-setters.

The PSRO statute, though, permits disclosure "to the extent necessary" to carry out the purposes[141] of the PSRO law. Yet, if rate-setting itself will carry out the purposes of the law, then the disclosure provision will permit rate-setters to get all the data they need to set rates. Since rate-setters hope to avoid the PSRO disclosure bar by engaging only in tasks that are consistent with the purposes of the PSRO law, they should get all the data they need.

Disclosure of PSRO information to rate-setters, therefore, might facilitate the achievement of the Congressional purposes behind the PSRO law. If the statutory basis for rate-setting required close cooperation with the Social Security Administration and

the determination of rates in a manner that promoted the effective use of hospital resources by Medicare patients, rate-setters would be pursuing goals very similar to the purposes of the PSRO legislation. The PSRO statute then would permit PSRO disclosure to rate-setters, and the third exemption of the FIA would not apply. A rate-setting body, if it were a state agency, would use the FIA to get PSRO data.

(b) Will the statutory bar suffice for FIA purposes?

A court might disagree that rate-setters with state statutory authority really would further the purposes of the PSRO law. It might interpret the purposes differently, or it might require a stronger and clearer link between the rate-setters' activities and the PSRO purposes. The court then would have to decide whether the PSRO statute was specific enough for the FIA.

Until recently, the courts clashed on the degree of specificity necessary to satisfy the FIA. Some courts held that any statute, no matter how vague or general, that prohibited disclosure would suffice for the FIA.[142] A majority of courts, however, insisted that the statute either provide standards to guide the agency's disclosure decisions, or identify the specific categories of undisclosable documents.[143]

A recent Supreme Court case, FAA v. Robertson [144], resolved this dispute among the lower courts. The Robertson case required the court to construe 49 USC 1504, the statute rendering certain CAB reports confidential. The statute gives the administrator of the FAA discretion to determine whether to release the reports. If someone objected to the release of the report, and if the FAA administrator determined that 1) release would harm the person who objected, and 2) the public interest did not require disclosure, then the FAA could not release the report.

The Court argued that Congress knew when it passed the FIA that other non-disclosure statutes conflicted with the public information statute.[145] Congress could harldy have intended to repeal them all by implication;[146] indeed Congress noted specifically in the accompanying report that the FIA would not modify these nondisclosure statutes.[147] The Court's examination of the legislative history reveals that "no distinction seems to have been made on the basis of the standards articulated in the exempting statute or on the degree of discretion which it vested in a particular Government official."[148]

Congress, then, did not intend to repeal 49 USC 1504. "Repeals by implication are disfavored,"[149] the Court noted, and it was not the province of the Court to override the legislative judgment.[150] Both statutes must stand, then, and both must remain effective. The FAA statute, therefore, would suffice to block disclosure under the FIA.[151]

The Robertson case would bar FIA disclosure to rate-setters if a court thought that the PSRO statute applied to them.

Courts need not trouble themselves determining whether the statute was specific enough. The only question a district court need answer is "the factual existence of such a statute, regardless of how unwise, self-protective, or inadvertent the enactment might be."[152]

The issue, then, appears settled. If a statute bars disclosure of agency records, it will be sufficiently specific under the IFA. Rate-setters can avoid this problem only if they can prove that the statutory bar does not apply to them, because disclosure of PSRO data to them would be "necessary to carry out the purposes of this part."

2. Confidential Commercial Information

> (b) "This section does not apply to matters that are -
>
> ...
>
> (4) trade secrets and commercial or financial information obtained from a person and privileged or confidential."[153]

Despite some initial difficulty in interpreting this section, the courts now agree that the fourth exception applies to trade secrets, and to information that is 1) commercial or financial, 2) obtained from a person, and 3) privileged or confidential.[154]

A hospital is a "person" within the meaning of the FIA.

(a) "Commercial" Information

This section protects only information that is "commercial or financial." The legislative history, regrettably, only obscures the meaning of the statute. The Senate report explains that the exemption protects information that people would not customarily disclose to the public, but do disclose by answering government questionnaires.[155]

The report continues:

> "This would include business sales statistics, inventories, customer lists, and manufacturing processes. It would also include information customarily subject to the doctor-patient, lawyer-client, lender-borrower, and other such privileges. Specifically it would include any commercial, technical and financial data, submitted by an applicant or a borrower to a lending agency in connection with any loan application or loan."[156]

This part of the report apparently contradicts the clear language of the statute, for it is hard to imagine how any information subject to the doctor-patient privilege really is "commercial" information. It is equally difficult to understand how the exemption covers technical data that is not financial, for the statute nowhere extends coverage to that data. The House Report - written after the House passed the bill - copies much of the Senate Report, but adds "explanatory" language that exceeds the scope of the statutory language.[157]

Kenneth Culp Davis, an eminent American authority on administrative law, also found the legislative history puzzling. "The reports on their face," he wrote, "appear to involve a flagrant attempt to defeat the plain meaning of the words 'commercial or financial.'"[158] Davis, who believes that the FIA should protect all confidential information, even though it actually does not, explained that

> "...the discrepancy between the statutory language and the reports turns out to be mere inadvertence. The Senate committee simply failed to alter its earlier report, based on an earlier bill without the words 'commercial or financial.' And the House committee seven months later copied most of the Senate report."[159]

He concluded:

> "Committee reports explaining the earlier version of the bill that did not include the words 'commerical or financial' do not seem to be a satisfactory basis for finding the meaning of the enacted version that did include those words."[160]

The legislative history, then provides little guidance for interpreting the statute. The courts have interpreted "commercial or financial" information to include cost data[161] and financial statements, sales volume, proposed bids, and market shares of company products,[162] cost-accounting principles,[163] sales statistics and profit and loss statements,[164] and data from loan applications.[165]

PSROs, though, will not collect any of these kinds of data. They will collect information on the diagnoses of patients, the length of the patients' stay in the hospital, the physician who attended the patient, and various procedures performed on the patient.[166]

These data do not resemble the commercial information with which other suits have dealt. But a hospital would argue that data on the hospital's case-mix would have a commercial impact, by indicating to other hospitals the internal allocation of hospital resources. Thus, the hospital would conclude, these data are commercial because they influence commercial decision-makers by providing information about other commercial decision-makers.

This argument, though, would render almost all information commercial, if it influences another firm to do anything in response to the disclosure. A broad definition of "commercial" would defeat the purposes of the FIA - i.e., to encourage maximum public disclosure - and would be inconsistent with the narrow interpretation that courts have given the statute.

The courts have provided little clear guidance about the boundaries of the words "commercial or financial." One district court has held, in Brockway v. Department of the Air Force,[167] that a report produced by Cessna, a private company, on the causes of a airplane crash is "commercial information" for FIA purposes. The court argued that Cessna was a commercial enterprise (i.e.,

primarily sought profit), that it would not want its competitors to see the report, and that any reports it produced therefore were commercial.[168]

That line of reasoning however, is hardly persuasive. The court would not argue that a press release announcing the retirement of Cessna's president would be "commercial information." Cessna, of course, would not want to prevent its competitors from seeing the press release, but fear of competition pertains more to the problem of confidentiality than to the problem of commercial information. The Brockway court would have determined whether the information was commercial, and then ascertained whether the information should be kept confidential because Cessna did not want to reveal its corporate failings to its competitors.

Only two other decisions illuminate the definition of "commercial information." One court has ruled that the names and addresses of employees are not commercial information.[169] The PSRO lists of the names of doctors at particular hospitals will not be "commercial information." More importantly, though, one court - in the Washington Research case - held that research designs and scientific proposals for grant applications are not "commercial information" because they are not used by profit-making enterprises, and are not used to produce or market a particular good or service.[170]

Neither PSROs nor rate-setters will be profit-making ventures; nor will they use PSRO data to "produce or market a particular good or service." They will use the data only for administrative purposes. If the courts adopt the Washington Research test, rather than the Brockway test, PSRO data will not be "commercial information," and the 4th exemption will not preclude PSRO disclosure.

A court could adopt the Brockway test, of course. Any data gathered from proprietary hospitals would be "commercial information" under that test, and probably would be protected. Non-proprietary hsopitals, a court might argue, need the same protection because they must compete with proprietary hospitals for patients and doctors. Therefore, the court could conclude that data from non-proprietary hospitals must be "commercial information" also.

(b) Confidential or Privileged Information

That determination, however, does not end the court's inquiry. The information also must be "confidential or privileged" before the 4th exemption of the FIA protects it. "Privileged" applies to evidence that would be inadmissable in court. "Confidential" information by contrast, involves some promise to safeguard the privacy of the person who provided the information.

PSRO probably would invoke the doctor-patient privilege to protect their information. Any information that the doctor-patient

privilege would protect in a courtroom, would be protected here; it is of course unnecessary for FIA purposes that someone actually seek the data in a court proceeding.

The issue, however, is not so simple. Doctor-patient privileges exist only by statutory creation; there is no such privilege at common-law. More than half the states have adopted statutes establishing a doctor-patient privilege.[171] Federal courts acknowledge a doctor-patient privilege only in cases in which they apply state law.

The FIA is, of course, a federal law. Federal courts hear FIA cases because the statute explicitly confers exclusive jurisdiction on the federal courts to hear such cases. Presumably, Congress intended federal courts to apply federal law when they heard FIA cases. Neither the Federal common law nor the new Federal Rules at Evidence[172] recognize any doctor-patient privilege, nor has Congress ever passed a statute creating it. Congress presumably intended that the federal courts would not use that privilege in FIA cases.

One could rest more easily with this conclusion if both Houses of Congress had not explicitly included the doctor-patient in their reports accompanying the FIA. Although the Davis analysis casts severe doubt on the usefulness of those legislative reports in construing this section, a nagging doubt remains. Congress may have intended that those states with a doctor-patient privilege should apply it in FIA proceedings, if the information at issue was "commercial or financial."

If the doubt also nags them, the courts will have to determine whether the doctor-patient privilege protects PSRO information. "The confidence which is protected is that only which is given to a professional physician during a consultation with a view to curative treatment."[173] The privilege would protect PSRO data about the particular diagnosis a doctor advanced, or the particular procedure he used. However, it would not protect the identity of the doctor, the number of visits the patient made or the dates on which he made them, or at any personal non-medical data about the patient.[174] The privilege would cover much information that rate-setters would want - if it applied.

It is unclear whether the doctor-patient privilege would forbid the release of statistical information that did not identify any individual. Since the policy behind the doctor-patient privilege seeks mainly to encourage patients to converse openly with their doctors, and to encourage doctors to respond freely,[175] it is hard to see how the release of aggregated data would undermine this policy. Although logic seems to argue that the doctor patient privilege would not prohibit the release of statistical information, a court might construe that privilege to mean that any data that once were privileged must remain so forever. The court then would forbid FIA disclosure.

The doctor-privilege, however, probably will not exempt PSRO disclosure, simply because there is no federal doctor-patient privilege. However, the FIA also permits non-disclosure if the commerical information is "confidential."[17]

A governmental promise of confidentiality would not suffice for FIA purposes.[176] The courts have defined information as "confidential" under the FIA only if 1) the person from whom the information was obtained would not customarily disclose it to the public, and 2) disclosure either a) would impair the government's ability to collect that information in the future

or b) would cause substantial harm to the competitive position of the person from whom the information was obtained.[177]

Hospitals do not customarily release to the public the information that PSROs will collect. PSRO data will be "confidential," then, if its release would impair the ability of PSROs to collect such data in the future, or would harm the hospital's competitive position. Since hospitals must provide information to PSROs if they wish to receive Medicare or Medicaid reimbursement, disclosure of PSRO data will not impair the ability of PSROs to collect hospital data.

A hospital, however, might argue that it must compete for patients and doctors, and that release of PSRO data will harm their competitive position. Disclosure of information about all local hospital, though, should not "substantially" harm the competitive position of any particular hospital. Moreover, as only 12% of all American hospitals are proprietary,[178] the courts may refuse to listen to hospitals pleas about their "competitive" position. Believing that the provision of health care has moved outside the market, courts may find no harm to hospital's competitive position, and will hold that PSRO data is not confidential. They will then compel disclosure.

Rate-setters still may be able to get even "confidential" information. If rate-setters do not need data that would permit them to identify individual doctors or hospitals, but can use aggregated data of some sort (e.g., local averages), they can get

PSRO data. If it is possible to delete identifying details in otherwise confidential information, the FIA demands disclosure.[179] Exception 4 protects only information that 'can't be rendered sufficiently anonymous by deletion of the filing party's name and other dientifying information."[180]

The courts have yet to define the level of detail that may be disclosed. They have recognized the "small number" problem: "in those cases in which the party that filed the statement is so large or unique that disclosure of the data itself would destroy the confidentiality of that party, it is conceivable that total non-disclosure would be justified."[181]

To resolve this problem, a court might weigh the importance of disclosure to rate-setters against the likelihood of identifiability and the seriousness of the resulting invasion of privacy. Rate-setters ostensibly would have a strong position, but a court could easily forbid disclosure rather than risk invading the privacy of a hospital or physician.

The 4th exemption, then, probably will not bar PSRO disclosure to rate-setters. PSRO data probably is not "commercial or financial" for FIA purposes because they will not be used for profit-making purposes. Even if the information is "commercial", it is not privileged; there is no federal doctor-patient privilege. The information probably falls outside the FIA definition of "confidential" as well, for a hospital would find it difficult to prove substantial harm to

its competitive position were the information disclosed.

3. Inter- and Intra-Agency Memoranda

(b) "This section does not apply to matters that are -

...

(5) inter-agency or intra-agency memorandums or letters which would not be available to a party other than an agency in litigation with the agency."[182]

Congress intended this exemption to protect the internal policy-making of agencies, by encouraging free and frank discussion among agency officials. This provision covers internal memoranda that contain advice, opinions, and recommendations, but it does not cover purely factual information, even if it is part of a memo that also contains advice. "Factual information may be protected only if it is inextricably intertwined with policy-making processes."[183] An agency must disclose factual data in memoranda unless the data cannot be "disentwined" from the policy advice in the memo.[184]

Rate-setters will be interested primarily in factual data, rather than in the opinions of PSRO members. It is hard to believe that PSROs will not first assemble factual data, and then make recommendations. Rate-setters, seeking only the factual data that

formed the basis for the recommendations, should have no trouble with this provision.

4. Medical and "Similar" Files

(b) This section does not apply to matters that are -

...

(6) personnel and medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."[185]

This provision represents the FIA's closest approach to a safeguard of personal privacy. Congress intended the provision to "protect individuals from public disclosure of intimate details of their lives."[186]

The courts have disagreed over the proper interpretation of exemption 6. The Fourth Circuit has held that "similar files" are those that contain 'intimate details" of a 'highly personal' nature." These fall within the 6th exemption and are never subject to disclosure.[187] The court has no discretion, argued the Robles court, to compel disclosure of "similar files." The Robles test serves the purposes of the FIA by severely limiting the definition of 'files' for the purposes of exemption 6, but by requiring non-disclosure of any files that did fall within that exemption.

The Third and DC Circuits, by contrast, use a two-leveled test. They first ask whether disclosure will in any way invade privacy, and then ask whether that invasion would be "clearly unwarranted."[188] These Circuits use an expansive definition of "files" but compel the disclosure of much information that falls within that definition. Thus, the Fourth Circuit invokes exemption 6 for only "highly personal" matters, but allows no disclosure of them, while the other two Circuits invoke exemption 6 for almost anything, but often compel disclosure of the files anyway. Indeed, both the DC and Third Circuits have held that names and addresses constitute "similar files" within the meaning of exemption 6.[189]

The Fourth Circuit test would bar PSRO disclosure only if the Court found that PSRO data contained "highly personal" or "intimate" details about patients or doctors. Rate setters do not need to know "intimate" details about identifiable patients, so only doctors could object to disclosure. A court would find the PSRO data to be "highly personal" if it construed that term to include anything of personal importance. The court would reach the opposite conclusion if it interpreted "highly personal" to include only details that would be personally embarassing - as distinct from professionally damaging - if revealed. It is hard to know whether doctors could block disclosure under the test of the Fourth Circuit.

The tests of the other two Circuits are equally difficult. If the rate-setters request aggregated data that do not contain identifying details of any kind - names, or descriptions of individual patients or doctors - then exemption 6 simply won't apply. If the rate setters demand information that does contain identifying details, the Third and DC Circuits apply a balancing test: would disclosure be a clearly warranted invasion of personal privacy?

The exemption safeguards only personal privacy - hospitals cannot object to disclosure.[190] Moreover, the courts have interpreted the words "clearly unwarranted" to mean that the courts should favor disclosure. The courts thus balance the public's interest in disclosure against the individual's interest in non-disclosure, while heavily weighting the former.[191] However, a court will not compel even a minor invasion of privacy - the release of names and addresses - when the interest in disclosure is only for private gain or commercial exploitation.[192] A court, however, will compel a minor invasion of privacy to facilitate a study of government agency - which is of greater public interest.[193]

If PSROs only disclosed the names of individual doctors, the DC and Third Circuits would follow Getman and compel disclosure. PSROs, however, can reveal more detailed information about physicians, so the court will have to balance the public interest in maintaining the quality of medical care against the greater invasion of physician privacy that PSRO disclosure would produce.

Finally, rate-setters do not need to know the names or titles of individual doctors, only the quality of care they deliver in a hospital. Yet, publication of PSRO norms - mandated by statute - would permit anyone to determine whether a particular physician has given "proper" care.[194] On balance, the case for PSRO disclosure is stronger than that for disclosure of the Civil Service Commission Reports,[195] but it is hard to tell whether it is strong enough.

D. Summary

Rate-setters will be able to use the FIA only if they are not federal agencies, and only if PSROs are federal agencies. Before Congress amended the FIA in 1974, the courts defined "agency" as federally-created organizations that exercise "substantial independent authority." PSROs probably should fall within this definition because their decisions will influence - possibly even direct - the flow of billions of federal dollars of Medicare and Medicaid reimbursement.

PSROs also should fall within the expanded definition of 'agency' in the newly-amended FIA. Congress intended to expand the coverage of the Act to corporations that perform government functions, or are government-controlled. PSROs will perform a government function: they will provide medical assessments of the care that Medicare and

Medicaid patients receive. PSROs will perform this function amidst numerous governmental limitations on their duties, functions, and corporate freedom. The government exerts this control through statutory restrictions on PSROs, and continuing oversight of PSROs by the Secretary of HEW.

If the FIA does apply to PSROs, they must disclose their records upon request - unless one of the enumerated FIA exemptions applies to the records. Only four of the nine exemptions possibly pertain to PSRO data. The exemptions merely permit, but do not require, non-disclosure. Few PSROs, however, would release their records unless legally compelled to do so, for the PSRO statute prescribes criminal penalties for the illegal release of information.

The third exemption - for specific statutory bars to disclosure - probably will prove troublesome. The PSRO statute limits disclosure to that necessary to carry out the purposes of the PSRO legislation. Rate-setters cannot have substantial authority under the Social Security Act without thereby becoming 'agencies' under the FIA. They will have some trouble, then, proving that they will be pursuing the purposes of the PSRO law. But if the state statute that underlies rate-setting directs them to help promote the effective use of Medicare resources, rate-setters may be able to persuade a court that they will be pusuing the purposes of the PSRO law. Since rate-setters then will pursue purposes that closely resemble the purposes of PSROs, the PSRO statute should not apply to the

disclosure of PSRO data to rate-setters. The third exemption of the FIA, therefore, does not prohibit disclosure to rate-setters, because that disclosure would violate no statutory provision.

A court might interpret the PSRO statute more narrowly, however, and hold that the statute prohibits disclosure to rate-setters. Under the recent Robertson decision of the Supreme Court, the statutory bar to disclosure in the PSRO law would suffice under the FIA. If a court finds that the statute applies to PSRO disclosure to rate-setters, then, the FIA will not compel disclosure.

Two of the other possibly applicable FIA exemptions should not prove as troublesome. The fourth exemption - for confidential commercial information - should not bar rate-setters. PSRO data probably falls outside the definition of "commercial information" that courts have used for the FIA. Even if PSRO data were confidential, they would not be "privileged", because there is no federal doctor-patient privilege. Nor would the information be "confidential" unless its disclosure would substantially harm the competitive position of the person from whom the information was obtained. Disclosure of information about all local hospitals presumably would not substantially harm the competitive position of any of them, so the information would not be "confidential" under the FIA.

The fifth exemption - for inter-agency memoranda - should not give rate-setters much pause. That exemption prohibits only the disclosure of opinions and recommendations, and does not apply to factual data. Since rate-setters will seek only factual data, the fifth exemption should not hinder them.

The sixth exemption - for private medical and 'similar' files - may prove to be the most difficult. PSRO records probably fall within the definition of 'files' for the purposes of the sixth exemption. A court then must decide whether disclosure of PSRO records would be a "clearly unwarranted" invasion of the personal privacy of physicians or patients. Presumably rate-setters will not want information that would enable them to identify individual patients; only doctors then would be able to object to disclosure, for only their privacy could be invaded. A court would have to weigh the seriousness of the invasion of the doctors' privacy against the public interest in controlling medical inflation and maintaining the quality of care. The FIA instructs the courts to favor disclosure, but a court might consider the invasion of doctors' privacy to be so serious that it would not compel disclosure.

IV. THE PRIVACY ACT OF 1974

Even if rate-setters could use the FIA to gain access to PSRO data, the Privacy Act of 1974[196] theoretically could impinge on the

transfer of PSRO data. The Act governs the accumulation, storage and transfer of data gathered by Federal Agencies. However, the restricted reach of the Act, and several of its exceptions make it seem unlikely that the Act will hinder rate-setters, regardless of the organization and legal status that the rate-setters enjoy.

The 93rd Congress passed the Privacy Act,[197] at the end of 1974, ostensibly to protect the privacy of citizens of the U.S. about whom federal agencies gather data. The Act applies to any federal organizations that might be considered "agencies" under the Freedom of Information Act. (FIA).[198]

The Privacy Act protects individuals, defined as citizens of theU.S., or aliens lawfully admitted for permanent residence.[199] The legislative history clearly indicates that the Act does not protect "proprietorships, businesses, and corporations[200], but only individuals. Hospitals, therefore, have no standing under this Act to object to PSRO disclosure.

The Act applies to data banks maintained by Federal agencies, and may apply to some databanks that state or local agencies, or private organizations, maintain on behalf of federal agencies. The legislative history indicates that Congress intended the Act to apply to personal information systems of state and local agencies, and private organizations, when the information systems "are specifically created or substantially altered through grant, contract, or agreement with federal agencies, where the agency causes provisions of the Act to be applied to such systems or files or relevant portions."[201]

If a PSRO is a federal agency under the FIA, then the Privacy Act applies to it. If a PSRO is a part of HEW, the Privacy Act applies to it. Even if a PSRO is a private organization, the Privacy Act still will apply,

for it covers federal contractors who collect data on behalf of a federal agency.[202]

The Privacy Act forbids disclosure of "records", except under certain specific circumstances. "Records" are information about an individual "that contains his name or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint, or a voice print, or a photograph."[203] The Act apparently requires very specific identifying information - information that by itself would enable someone to identify the individual about whom the information was collected.

Rate-setters do not need nor want information that is so detailed. They certainly do not want records that would enable them to identify individual patients. Nor do they need to know the names or code numbers of particular physicians; they will probably be satisfied to be able to see patterns of health care.

Rate-setters, of course, might in the future want information that identifies individual physicians. Even if the Privacy Act does apply to the records that rate-setters request, four exceptions to the Act probably will allow rate-setters to get the information - regardless of the legal basis for rate-setting. Section (b) of the Act provides that an agency shall not disclose any record to any person, or agency, without the consent of the person(s) whom the record describes, except in certain circumstances, some of which will help rate-setters get PSRO records despite the Privacy Act."[204]

The agency may disclose the record "to those officers and employees of the agency which maintains the records who have a need for the record in the performance of their duty".[205] If the PSROs and rate-setters are part of the same agency - HEW, say - a rate-setter could get PSRO records to

perform his duty - i.e., to set rates. HEW fits within the FIA definition of "agency", so the Privacy Act presumably would permit transfer of records within HEW - even if the transfer went from PSROs (arguably an agency under the FIA) to rate-setters in SSA (itself an agency under the FIA). The drafters of the Privacy Act probably did not intend to permit the transfer of information between agencies that are part of a larger agency; the statutory language nonetheless permits it.

An agency may also disclose a record if it would be "required under section 552 of this title."[206] Section 552 of Title 5 is the FIA. The Privacy Act thus permits an agency to disclose records whenever the FIA requires it. The FIA requires disclosure whenever an agency fails to show that its records fall within one of the 9 specific exceptions to the FIA. Thus, if a rate-setter can get PSRO records under the FIA, the Privacy Act does not bar disclosure. If the FIA does not require disclosure, the Privacy Act creates an additional barrier. (Agencies, of course, have little interest in disclosing records that they need not disclose; one might well wonder if the Privacy Act has accomplished much by creating a new barrier to disclosure when internal agency incentives already work in that direction.)

An agency conceivably could disclose a record under the FIA even though the FIA does not require disclosure.(FIA exceptions permit, but do not require, non-disclosure). Two other provisions of the Privacy Act thus become important. An agency may disclose information for a "routine use".[207] A "routine use" is defined

as the use of a record "for a purpose which is compatible with the purpose for which it was collected."[208] This provision, a bureaucratic loop-holer's dream, must be read in conjunction with the provision that permits an agency to gather information only if the information is necessary to accomplish a purpose of the agency that is required by statute or executive order.[209] Nonetheless, this provision will permit a flood of data to escape an agency.

Rate-setters should plunge into the flood. They will use PSRO data in a manner compatible with the uses for which the data were collected. Indeed, rate-setters's use of the data may even be "necessary to carry out the purposes" of the PSRO legislation. Thus, if rate-setters were a federal agency, they could use PSRO data for a "routine use" - and the Privacy Act would not bar disclosure.

An agency also may disclose information "to a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable."[210] A statistical record is one used only for research or reporting purposes, and not used to make "any determination about an identifiable individual."[211]

Rate-setters might use this provision to gain access to PSRO records, if the rate-setters ask only for aggregated data, or, at the very least, for information that does not permit them to identify individual patients or doctors. If rate-setters insist on using PSRO data to make determinations about individual doctors, they will not be able to use this exception to the Privacy Act. But they need use this section only if they will not be a federal agency or part of a federal agency, and if the FIA doesn't permit them to get PSRO data.[212]

The Privacy Act should pose no problems for rate-setters if they try to get PSRO data. Although the Act will probably apply to PSROs, it probably will not apply to the kind of records that PSROs will keep. Even if it does apply to the kind of records that PSROs keep, rate-setters should be able to gain access to PSRO records regardless of the organizational form that the rate-setting commission takes. If the PSROs and the rate-setters are part of the same agency, then exception 1 - providing for intra-agency transfer - should permit access to PSRO data. If the rate-setters are a separate federal agency, then they should be able to gain access under exception 3 - which permits disclosure for "routine uses". If a rate-setter is not a federal

agency, it should be able to get the information under exception 2 - concerning the FIA - or exception 5 - concerning "statistical uses." In any case, the Privacy Act should not hinder rate-setters.

FOOTNOTES

1. 42 USC 1320c-14, 1320c-15. For the entire law, see Appendix III

2. See Appendix I. HEW regards these "proposed regulations" as "policy statements," but the final regulations probably will resemble the "policy statements" quite closely.

3. 42 USC 1320c-15.

4. Id., 1320c-6, (release of reports concerning providers that violate provisions of PSRO law).

5. Id., 1320c-14. (emphasis added).

6. US Dept. of HEW, Bureau of Quality Assurance, Specifications for Confidentiality Policy on PSRO Data and Information (1975) Definition G. ("PSRO Review System"), [Hereinafter cited as Specifications]

7. Id., Definition C, ("identifiable data").

8. Id., Policy Statements 2-4

9. Id., Policy Statements 11-15

10. Id., Policy Statements 16-24

11. Id., Definition G.

12. Id., Policy Statement 6

13. Id., Policy Statement 6 and 22

14. 42 USC 1320c-14(b) (emphasis added).

15. Sen. Bennett (R-Utah) introduced the PSRO statute on the floor of the Senate, as an amendment to H.R. 1 (PL. 92-603), which has a compendium of amendments to the Social Security Act. 117 Cong. Rec. 1017 (1971). Bennett introduced his amendment after the House had reported out the Social Security Amendments, so the House report that accompanied HR1 did not mention PSROs. The report of the Senate Finance Committee, therefore, provides most of the guidance as to the legislative intent behind the PSRO law.

16. S. Rep. No. 1230, 92nd Cong. 2nd Sess., 265 (1972), [Hereinafter cited as Senate Report].

17. Specifications, supra n. 6, Definition G. Medicare intermediaries help administer Medicare Part A, pursuant to agreements under section 1816 of the Social Security Act (42 USC 1395h) (Blue Cross is an intermediary). Medicare carriers help administer Medicare Part B, pursuant to agreements under Section 1842 of the Social Security Act (42 USC 1395u), (Blue Shield is a carrier). The PSRO law requires the interchange of data between PSROs and intermediaries [42 USC 1320c-14(a)(1)] and between PSROs and carriers [42 USC 1320c-14(a)(2)].

18. It is hard to imagine how data processors could process PSRO data if PSROs refused to share data with them.

19. Specifications, supra, n. 6, Definition G.

20. Id.

21. 42 USC 1320c-14

22. Id. 1320c

23. Id., 1320c-14.

24. Id., 1320c-15.

25. Id., 1320c-14

26. Interview with Duke McCloud, a lawyer in the Bureau of Quality Assurance, US Dept. of HEW, 31 July 1975. (interview notes on file with author, hereinafter cited as McCloud.) The BQA in general, and Mr. McCloud in particular, is drafting the PSRO regulations on disclosure.

27. Id.

28. 42 USC 1320c-14.

29. Id.

30. Id.

31. McCloud, supra, n. 26

32. 42 USC 1320c-7.

33. Some hospitals or physicians might even prefer to have PSRO data disclosed, to substantiate their claim that they are providing better - and therefore more costly-services.

33a. 42 USC 1320c-1(b)(1)(B),(b)(2), (c)(2)(C).

34. McCloud, supra n. 26.

35. 42 USC 1320c-7

36. Specifications, supra n. 6, definition F

37. Id, Definition F.

38. Id. Guideline 6. This requirement tracks the language of the PSRO statute, which forbids disclosure except "to the extent that may be necessary to carry out the purposes of this part" 42 USC 1320c-15. Thus an agency can use PSRO data only if

necessary to carry out the purposes of the PSRO legislation (see discussion in text at pp. 46-49, and then only to the extent necessary to carry out those purposes.

39. Id., Guideline 24

40. Id., Guideline 25

41. Id., Definition D

42. Id., Guideline 17.

43. Id., Guideline 22.

44. Id., Guideline 22.

45. Id., Definition C (emphasis added).

46. McCloud, supra n. 26. Thus, the regulations permit release of information gathered from each of six doctors in theobstetrical department of a hospital, as long as the information is tabulated for the department asa whole, and not for the particular doctors in it.

47. Even that explanation is less than crystalline. A clearer phrasing might be: Data and information are "identifiable" if and only if they
1) are collected about or tabulated on a particular individual,

2) are separate from data and information about any other individuals, and
3) identify that particular individual either explicitly or by implication.

48. McCloud, supra n. 26.

49. Office of Professional Standards Review, US Dept. of HEW, PSRO Program Manual (1974). [Hereinafter cited as Manual].

50. Id., sec. 705.31

51. Id., sec. 705.34(e).

52. McCloud, supra n. 26

53. Manual, supra n. 49, sec. 106

54. This is, in some ways, a self-fulfilling prophecy. If HEW steadfastly opposes expanded disclosure, it will buttress the position of those who already oppose any PSRO disclosure. HEW might create the very political opposition that it claims would undermine the effective implementation of the PSRO law.

55. National Health Planning and Resources Development Act of 1974, PL 93-641, Sec. 1513 (1975).

56. S USC 552. See Appendix II

57. See S. REP. NO. 1183, 89th Cong., 2nd Sess., 1-4 (1966)

58. 112 CONG. REC. 13,647 (1966) (remarks of Congressman Laird).

59. S. REP. NO. 1183, 89th Cong., 2nd sess., 3 (1966).

60. Never a model of legislative drafting, the FIA was amended the following year. PL 90-23 (1967).

61. Katz, The Game Bureaucrats Play: Hide and Seek Under the Freedom of Information Act, 48 TEX L. REV. 1261 (1970); Nader, Freedom from Information: The Act and the Agencies, 5 HARV. CIV. RIGHTS-CIV. LIB. L. REV. 1. (1970).

62. 5 USC 552 (a)(1).

63. Id. 552 (a) (2).

64. Id., (a)(3).

65. Id., (a) (4)(B).

66. Id. 552(b)

67. Id. 551(2). (emphasis supplied).

68. Id. 552(e).

69. H.R. REP. NO. 876, 93rd Cong., 2nd sess., 7 (1974).

70. S. CONF. REP. NO. 1200, 93rd Cong., 2nd sess. 13 (1974).

71. 42 USC 1320c-4(f)(2)

72. Manual, supra n. 49, Chapter VI.

73. It is not clear which test is appropriate. The House version was the only one that both houses of Congress saw when they passed the bill; presumably it reflects the bill that Congress thought it passed. Yet, the Conference Report represents the understanding that the conferees of each house had in reconciling the 2 versions of the bill, and influenced Congress when it passed the amended amendments. I will discuss both tests.

74. McCloud, supra n. 26.

75. SENATE REPORT, supra, n. 16, 254.

76. Id.

77. Id. at 256 (emphasis added).

78. 42 USC 1320c

79. Id. 13206c-1(b)(2)

80. McCloud, supra n. 26.

81. 42 USC 1320c-1(b).

82. Id., 1320c-4 (a)(1).

83. Id. 4 (a)(2).

84. Id. 4(a)(4)(5).

85. Id. 1320c-5(a).

86. Id. (4)(a)(3).

87. Id. 1320c-10.

88. Id. 1320c-a(b).

89. Id. (a)(b)(4).

90. Id. 1320c-1(a).

91. Id. 1(b).

92. Id. 1320c-1(a)(2); id. 1(c);

93. Id. 1320c-4(f)(1)(A).

94. Id. 4(g).

95. Id. 4(f)(1)(B).

96. Washington Research Project, Inc. v. Dept. of HEW 504 F. 2d 238, (DC Cir., 1974, petition for cert. filed, 43 USLW 3432) (US, Feb. 4, 1975)(No. 74-736).

97. Id. at 248 (emphasis supplied).

98. Id.

99. 42 USC 1320c-7.

100. Id. 1320c-8.

101. This difference was crucial in Washington Research. The Supreme Court, though, is deciding whether to hear and appeal, and their decision could change the analysis I have outlined above. But if they affirm the Appellate Court's decision, it still would be perfectly consistent to hold that IRGs are not agencies, although PSROs are.

102. Soucie v. David 448 F. 2d 1067 (D.C.Cir., 1971) (emphasis added). The Soucie test refers to the independent exercise of authority within an agency, rather than the exercise of power independent of government control. In Soucie, for example, the court held that the Office of Science and Technology was an agency, even though it was part of the White House.

103. See 5 USC 551 (1).

104. Skolnick v. Campbell 454 F. 2d 531 (7th Cir., 1971) (National Commission on the Causes and Prevention of Violence is an agency); Skolnick v. Kerner 435 F 2d 694 (7th Cir., 1970)(National Advisory Commission on Civil Disorders); Skolnick v. Parsons 397 F. 2d 523 (7th Cir., 1968)(President's Commission on Law Enforcement and the Administration of Justice); and Amalgamated Meat Cutters v. Connaly 337 F. Supp. 737 F. Supp. 737 (DDC, 1971) (Cost of Living Council).

105. Soucie supra n. 102 at 1073.

106. Soucie supra n. 102 at 1074-5.

107. See Freedman, Administrative Procedure and the Control of Direct Foreign Investment, 119 U.PA. L. REV. 1, at 9 (1970).

108. 5 USC 552 (a)(3).

109. Id. 552(a)(1).

110. Id. 552(a)(6)(A).

111. Id. 552(a)(4)(B).

112. Id.552(a)(4)(C).

113. Id. 552(a)(4)(B).

114. Id. 552 (b)(1) - (9).

115. Id. 552(c). (emphasis added).

116. Soucie, supra n. 102 at 1080.

117. See DAVIS, ADMINISTRATIVE LAW TREATISE, sec. 3A.5 (Supp., 1970). Conceivably, a PSRO could disclose data covered by one of the exemptions. That disclosure, however, is unlikely. PSROs may feel political pressure from hospitals and physicians who wish to block disclosure. More importantly, the contract that the PSRO might sign with the Secretary of HEW may forbid any disclosure not required by statute of regulation.

118. See the discussion in Vaughn v. Rosen, 484 F.2d 820, at 826 (DC Cir., 1973).

119. 5 USC 552 (b) (3).

120. 42 USC 1320c-15.

121. Manual, supra n. 49, sec. 108 (emphasis added).

122. McCloud, supra n. 26.

123. The HEW argument sounds somewhat like saying that the purpose of the Medicare Act was to enrich Blue Cross and Blue Shield.

124. 42 USC 1320c.

125. SENATE REPORT, supra n. 16, 254.

126. Id.

127. 42 USC 1395 x(k).

128. SENATE REPORT, supra n. 16, 255.

129. Id.

130. Id. at 256

131. 118 CONG. REC. s16111(1972)(Remarks of Sen. Bennett).

132. SENATE REPORT, supra n. 16, 54.

133. Ass'n of Am. Physician and Surgeons v Weinberger Civil No. 73 C 1653 (N.D. Ill., decided 8 May 1975) (3judge court) at 12.

134. Id. at 16.

135. Section 220 of the 1972 Social Security Act amendments (P.L. 92-603) provides an example. The federal government will fund state rate-setting experiments.

136. National Health Planning and Resources Development Act of 1974, PL 93-641 (1975), codified at 42 USC 300K et. seq.

137. 42 USC 300 l - 2(b).

138. Id. 300 l - l(b)(1).

139. Id. 300 l - 2(e).

140. Id. 300 l - 2(a). Of course, Congress could simplify matters for rate-setters by requiring PSROs to share their data with rate-setters. The 1974 Health Planning Act is another good precedent for this, for Congress there required PSROs to share their data with HSAs. Id. 300 l - 2(d). Congress could of course do the same for rate-setters.

141. The statute permits only such disclosure as may be 'necessary' to carry out the purposes of the law. Yet courts have never limited the meaning of 'necessary' to "that which is required". They have interpreted 'necessary' instead to include means that are "plainly adapted" to a particular end. See e.g., McCulloch v. Maryland 17 US (4 Wheat) 516 (1819). Disclosure of PSRO data to rate-setters would be "plainly adapted" to the purposes of that statute, and so should not be prohibited by that law.

142. California v. Weinberger, 505 F. 2d 767 (9th Cir., 1974) (42 USC 1306(a), which forbids any disclosure except as the Secretary of HEW provides, is specific enough for FIA purposes.)

143. Schecter v. Weinberger 506 F 2d 1276 [DC Cir., 1974) (42 USC 1306(a) is too broad for FIA purposes]. Accord: Stretch v Weinberger, 495 F 2d 639 (3rd Cir., 1974); Serchuk v Weinberger 493 F 2d 663 (5th Cir., 1974).

144. Administrator, FAA v Robertson, 95 S Ct. 2140 (1975).

145. Id. at 2148.

146. Id. at 2147

147. Id.

148. Id. at 2146

149. Id. at 2147

150. Id. at 2148.

151. Id.

152. Id. at 2149 (Stewart J., concurring) (quoting EPA v. Mink, 410 US 73, 95.)

153. 5 USC 552 (b) (4).

154. National Parks and Conservation Ass'n v. Morton, 498 F. 2d 765 (DC Cir., 1974) Getman v NRLB, 450 F 2d 670 (DC Cir., 1971); Consumers Union v Veteran's Administration 30] F. Supp. 796 (S.D.N.Y., 1969) appeal dismissed as moot 436 F 2d 1364 (2nd Cr., 1970).

155. SEN. REP. NO. 1183, 89th Cong., 2nd Sess., 9(1966).

156. Id.

157. H.R. REP. NO. 1497, 89th Cong. 2nd sess., 10(1966).

158. Davis, The Information Act: A Preliminary Analysis, 24 U. CHI. L. REV. 761, at 790 (1967) (hereinafter cited as Davis.)

159. Id. at 791

160. Id.

161. National Cable Television Assoc. v FCC 479 F 2d 183 (DC Cir. 1973).

162. Sterling Drug v FTC, 479 F. 2d 183 (DC Cir., 1973).

163. Petkas v Staats 501 F. 2d 887 (DC Cir., 1974).

164. Fisher v Renegotiation Board 473 F 2d 109 (DC Cir., 1973)

165. Rural Housing Alliance v Dept. of Agriculture, 498 F. 2d 73 (DC Cir., 1973).

166. See Task Force on PSRO Information System Models, U.S. Dept. of HEW, Report for Coordinating Committee, Appendix F (1974).

167. Brockway v Dept. of Air Force 370 F Supp. 738 (N.D. Iowa, 1974)

168. Id.

169. Getman, supra n. 154.

170. Washington Research Project, Inc. v Dept. of HEW 366 F Supp. 929, at 936 (DDC, 1973), aff'd in part, rev'd in part, 504 F 2d 238

(DC Cir., 1974) petition for cert. filed 43 USLW 3432 (US, Feb. 5, 1975) (no. 74-736); The Appellate Court specifically agreed with the lower court's finding that research designs are not "commerical or financial." 504 F. 2d at 245.

171. See 8 WIGMORE, EVIDENCE sec. 2380, n. 5 (McNaughton ed., 1961) (hereinafter cited as WIGMORE).

172. 88 STAT. 1926.

173. WIGMORE, supra n. 171, sec. 2382

174. Id., sec. 2384.

175. Id.

176. Bristol-Meyers v. FTC 424 F. 2d 935 (DC Cir., 1970.)

177. National Parks, supra n. 154 at 770.

178. House Committee on Ways and Means, Basic Facts on the Health Industry 92nd Cong., 1st sess., 43 (1971) (Comm. Print)

179. Fisher v Renegotiation Board, supra. 164.

180. National Cable Television, supra n. 161, at 195.

181. Id. at 194. (dictum). See also Pacific Architects and Engineer, Inc., v Renegotiation Board, 505 F. 2d 383, at 385 (dictum).

182. 5 USC 552 (b)(5).

183. Soucie, supra n. 102, at 109.

184. Fisher, supra n. 164 at 109.

185. 5 USC 552 (b) (6).

186. Rural Housing, supra n. 165, at 77.

187. Robles v EPA 484 F. 2d 843, at 845 (4th Cir., 1973).

188. Wine Hobby USA v IRS, 502 F. 2d 133 (3rd Cir., 1974). Getman, supra n. 154.

189. Wine Hobby, supra n. 188; Getman, supra, n. 154.

190. See Davis, supra, n. 158, at 799.

191. Getman, supra n. 154.

192. Wine Hobby supra n. 188.

193. Getman, supra n. 154.

194. Vaughn v Rosen, 383 F. Supp. 1049 (DDC, 1974), on remand from 484 F. 2d 820 (DC Cir., 1973) cert. denied, 415 U.S. 977.

195. The "small number problem" surfaces here. Rate-setters might be able to identify one doctor's practices simply by looking at a list of the hospital's staff, and the PSRO data.

196. 5 USC 552a.

197. P.L. 93-579.

198. 5 USC 552a (a)(1).

199. Id. 552a (a) (2).

200. U.S. Code Cong. and Adm. News, 93rd Cong., 2nd Sess., at 6993 (1974).

201. Id. at 6932.

202. 5 USC 552a (m).

203. Id. 552a(a)(4).

204. Id. 552 a(b).

205. Id. 522a (b)(1).

206. Id. 552(b)(2).

207. Id. 552a(b)(3).

208. Id. 552a(a)(7).

209. Id. 552a(e)(1).

210. Id. 552a (b)(5).

211. Id. 552a(a)(6).

212. The small number problem again emerges. If, for example, only two doctors perform brain surgery in a particular hospital, information about the choice of technique in a particular operation would allow one to determine which doctor had performed the operation. Arguably, the Privacy Act does not apply to that kind of information - i.e., about the choice of technique in a particular operation. But if it does, and if the Act defines "individually identifying" as including information that would facilitate in any way the identification of an individual, then a doctor or patient could use the Privacy Act to block disclosure.

APPENDIX I

DRAFT OF PSRO REGULATIONS

February, 1975

For the purposes of this paper, the following definitions shall apply:

A. PSRO Data and Information

Data and information which is acquired and/or generated by any PSRO.

B. Individual PSRO Data and Information

Computer or hard copy data and information identifiable to a specific individual.

C. Identifiable Data of Information

Data and information collected, generated or aggregated on a particular individual which identifies that individual either explicitly or by implication.

D. Privileged Data and Information

Medical data and information identifiable to an individual patient, data and information indicating patterns of health care practices identifiable to individual health care practitioners, records of PSRO determinations identifiable to individual health care practitioners and data and information collected and/or generated for MCE studies as defined in department regulations and guidelines.

E. Monitoring

The review and appraisal of PSRO functions.

F. Evaluation

The determination of program effectiveness and the impact of the PSRO program on quality of care and utilization of services.

G. PSRO Review System

A system comprised of the PSRO and all supporting components which assist the PSRO in the review process or are furnished PSRO data for

administrative purposes under Titles 18, 19, and 5 of the Social Security Act. The system may include (but is not limited to):

1. Hospital(s) if delegated review authority
2. PSRO review coordinator(s) - individuals responsible for carrying out PSRO activity within the health care facility
3. Medicare Intermediary(s)
4. Independent Health Data System(s), e.g., discharge abstract service
5. The PSRO
6. Medicaid State Agencies and Fiscal Agents
7. PSRO Contractors (any independent vendors providing data or data processing services to the PSRO)
8. Medicare Carriers
9. Other PSROs
10. DHEW
11. PSRO Support Centers
12. State PSRO Council
13. State Maternal and Child Health Agencies (Title V)

H. Health Care Practitioners

Physicians and other health care practitioners who are reimbursed for services through Medicare, Medicaid, or Maternal and Child Health programs.

I. Health Care Facilities

Organizations and institutions involved in the delivery of health care services (e.g., hospitals, nursing homes, outpatient facilities, etc.)

J. Sanction Proceedings

Procedures under Section 1157 and 1160 of the Social Security Act commencing with the forwarding of a sanction report by the PSRO under Section 1157.

K. PSRO Deliberations

Minutes of meetings, notes, comments, or other forms of recordings which evidence internal PSRO discussions pertaining to review or sanctions.

POLICY STATEMENTS

Notification to Public

The PSRO must establish and implement a procedure for public notification of the existence, scope and purposes of PSRO data system.

Notification to Patients, Practitioners, and Providers

The PSRO must establish and implement procedures to inform individual patients, health care practitioners and health care facilities on whom PSRO data and information has been or is being collected as to:

a. the name, title and address of the person immediately responsible for the PSRO data system
b. those who will have access to the file
c. the circumstances under which and the purposes for which PSRO data and information will be disclosed

The procedures for notification should be administratively efficient, but provide at a minimum for general notification of the above.

Obtaining Access to own PSRO Data and Information

Subject to restrictions on disclosure of PSRO deliberations (see #19), patients, health care practitioners and health care facilities must be allowed access, upon request, to their individual PSRO data and information for purposes of ascertaining the accuracy of that data and information. The PSRO must establish and implement procedures to verify the accuracy of the data and information; the data and

information to be accessed shall not be physically removed and/or transmitted outside of the PSRO.

4. Patient Access: Special Procedures

When a patient requests access to PSRO data and information under paragraph 3 above, the physicians of record must be notified in writing at least ten working days prior to patient access. The patient will not require physician authorization to access his individual PSRO data and information nor can the physician prevent patient access to the data and information. However, if upon receiving notification of intended patient access, a physician of record objects to the release of such information without clarification, he or his designee may be present when the patient accesses his individual file to make such clarification.

5. Limitation on Data Collection

The PSRO or any agent, organization or institution acting on its behalf as a collector, processor and/or reviewer of information must limit the collection of PSRO data and information to that necessary for the purposes of PSRO review and/or evaluation.

6. Limitation on Data Access

Each component of the PSRO review system will have access only to that PSRO information and data necessary to carry out its functions within the system.

7. Limitations on Establishment of a National PSRO Data Base

Privileged data and information shall not be stored in a manner which constitutes creation of a national PSRO data base.

Codification of Personal Identifiers

Identification of individual patients, health care practitioners and health care facilities on PSRO generated reports and forms must be in a coded form except for verification purposes as provided for in paragraph 3 above. Index files containing cross reference of codes to names of patients, practitioners and facilities will be maintained in a secure manner within the PSRO review system.

Purgation: Computer Files

Computer files may be maintained indefinitely; however, each PSRO must purge such files of all personal identifiers as soon as such identifiers are no longer necessary (guidelines recommending time periods will be developed) for purposes of review, appeals, program monitoring and program evaluation.

Purgation of Hard Copy

Privileged information maintained in hard copy must be purged when that information has served the specific purpose for which it was generated.

Responsibility for Confidentiality Vested in a Single Individual

A single individual within the PSRO must be assigned the responsibility for maintaining the confidentiality of PSRO data within the PSRO review system and for the notification to DHEW of any breaches of confidentiality within the review system. A plan for implementing this responsibility will be submitted to DHEW for approval.

12. Responsibility of Officers and Employees

All officers and employees of the PSRO and components of the PSRO review system must be made aware of their responsibility to maintain the confidentiality of PSRO data and information and of the legal penalties which may be assessed for unauthorized disclosure of PSRO data or information (i.e., fined not more than $1,000 and/or imprisoned not more than six months, under section 1166(b) of the Social Security Act).

13. Authorized Access: Requirements

An individual officer or employee of a component of the PSRO review system may not be authroized access to privileged PSRO data and information until that individual:

a. Has completed a training program in the handling of such data and information pursuant to paragraph 14 below; and

b. Has signed a statement indicating that: (1) the individual recognizes his responsibility to hold the data in confidence, and (2) is aware of the legal penalties which may be accessed for unauthorized disclosure of such data and information (i.e., fined not more than $1,000 and/or imprisoned not more than six months).

14. Training Requirements

It is the responsibility of the PSRO to provide an ongoing program of training in the handling of PSRO privileged information for those officers and employees of PSRO review system components authorized to handle such data.

5. Access to Hard Copy

Each access to privileged data and information which requires removal of the data or information outside of a PSRO review system component, must be recorded in such a manner as to indicate what material was accessed, purpose, when, by whom, where the material was taken, and when returned. A separate log shall be kept recording access to the index code file (see paragraph 8). This log shall indicate the purpose of access, when, and by whom.

6. Disclosure: Licensing Boards

Copies of sanction reports forwarded to the Secretary of DHEW under Section 1157 of the Social Security Act may at the same time be forwarded to state licensing boards. However, the practitioner or facility must be notified in writing at least 15 working days prior to disclosure to permit the submission of a statement to accompany the disclosed sanction report. If the licensing board has been forwarded a copy of a sanction report, the PSRO shall inform the licensing board of the DHEW determination within a reasonable time after determination is made.

7. Disclosure: Civil litigation

Subject to regulations governing administrative hearings under section 205(b) of the Social Security Act, privileged data and information, PSRO sanction reports and PSRO deliberations shall not be subject to subpoena or discovery proceedings in any civil action; nor shall any PSRO member, employee or consultant be subject to subpoena or discovery proceedings for the purpose of obtaining information relating to the above.

18. Disclosure: Claims Appeals

In claims appeals disclosure of privileged data or information to other than the claimant or his representative must be limited to those parties involved in the appeals process.

19. Disclosure: PSRO Deliberations

PSRO deliberations concerning patients, practitioners and facilities which serve as a basis of PSRO decisions shall not be disclosed outside the PSRO.

20. Disclosure: Sanction Proceedings

Subject to regulations governing administrative hearings under section 205(b) of the Social Security Act, and provisions for judicial review, privileged data and information and sanction reports may be disclosed for purposes of sanction proceedings, but disclosure is limited to physicians or facilities subject to sanction or their representatives, the appropriate Statewide Council for purposes of review and comment, and the Secretary or his authorized representatives for purposes of sanction determinations.

21. Disclosure: Results of Sanction Proceedings

If sanctions are levied on health care practitioners or health care providers by the Secretary pursuant to Section 1160 (b)(2), the name of the sanctioned party, the action taken and the nature of the sanction must be made a matter of public record by both the Secretary and the PSRO.

22. Disclosure: Monitoring, Review and Evaluation

For purposes of Federal and State program monitoring, review, and evaluation, privileged data and information may only be accessed by on-site visits to the PSRO or the other components of the PSRO review system in which the privileged data and/or information is stored. Privileged information or data may not be physically removed and/or transmitted outside of the PSRO review system except for the purpose of appeals or sanctions. Pursuant to paragraph #8 all privileged information and data needed for monitoring and program review purposes must contain all personal identification in a coded form.

23. Disclosure: Health Care Facility Information

Non-privileged data and information acquired and/or generated by any PSRO, its agents or ancillary components supporting PSRO review which is uniquely identifiable to a given health care facility may be disclosed upon request and payment of a fee to cover the expense of copying the requested information. However, the health care facility must be notified in writing 30 days prior to disclosure to permit the facility to review the information for accuracy and to provide comments to accompany the disclosed information.

24. Disclosure: Non-Privileged Information

Non-privileged information and reports generated within the PSRO may be disclosed to individuals, organizations and institutions upon request and payment of a fee to cover the expense of copying the requested information.

25. Specific Requests for the Generation of Non-Privileged Information

Specific requests for the generation of non-privileged information for research, evaluation and health planning purposes to be conducted by parties independent of the PSRO program will be processed on request and payment of a fee to cover the expense of producing the requested information subject to efficient program administration.

26. Freedom of Information Act

Reports generated by the PSRO containing information required by Federal agencies in their monitoring and program review capacity are considered to come under the Freedom of Information Act and once received by DHEW are subject to its disclosure provisions.

27. Disclosure: Other

Disclosure or access other than that described in this policy must be referred to the Secretary of HEW.

APPENDIX II

THE FREEDOM OF INFORMATION ACT

ATTACHMENT C -- Freedom of Information Act as Amended
in 1974 by Public Law 93-502
(Amendments are underscored)

§552. Public information, agency rules, opinions, orders, records, and proceedings.

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public--

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying--

(A) final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;

(B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and

(C) administrative staff manuals and instructions to staff that affect a member of the public;

unless the materials are promptly published and copies offered for sale. To the extent required to prevent a clearly unwarranted invasion of personal privacy, an agency may delete identifying details when it makes available or publishes an opinion, statement of policy, interpretation, or staff manual or instruction. However, in each case the justification for the deletion shall be explained fully in writing. Each agency shall also maintain and make available for public inspection an index of all [illegible] providing identifying information for the public as to any matter issued, adopted, or promulgated after July 4, 1967, and required by this paragraph to be made available or published. Each agency shall promptly publish, quarterly or more frequently, and distribute (by sale or otherwise) copies of each index or supplements thereto unless it determines by order published in the Federal Register that the publication would be unnecessary and impracticable, in which case the agency shall nonetheless provide copies of such index on request at a cost not to exceed the direct cost of duplication. A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if--

(i) it has been indexed and either made available or published as provided by this paragraph; or

(ii) the party has actual and timely notice of the terms thereof.

(3) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, each agency, upon any request for records which (A) reasonably describes such records and (B) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(4)(A) In order to carry out the provisions of this section, each agency shall promulgate regulations, pursuant to notice and receipt of public comment, specifying a uniform schedule of fees applicable to all constituent units of such agency. Such fees shall be limited to reasonable standard charges

for [illegible] duplication and provide for re-
[illegible] direct costs [illegible] and multi-
[illegible] shall be [illegible] manner either or at
[illegible] procedures that waiver or
[illegible] is to the public interest [illegible] consum-
[illegible] integrity [illegible] primarily
[illegible] public funds.

(4) To enjoin the district court of the United States [illegible] in which the complainant resides, or has [illegible] in which the agency records are situated, or in the District of Columbia, has jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld from the complainant. In such a case the court shall determine the matter de novo, and may examine the contents of such agency records in camera to determine whether such records or any part thereof shall be withheld under one of the exemptions set forth in subsection (b) of this section, and the burden is on the agency to sustain its action.

(C) Notwithstanding any other provision of law, the defendant shall serve an answer or otherwise plead to any complaint made under this subsection within thirty days after service upon the defendant of the pleading in which such complaint is made, unless the court otherwise directs for good cause shown.

(D) Except as to cases the court considers of greater importance, proceedings before the district court, as authorized by this subsection, and appeals therefrom, take precedence on the docket over all cases and shall be assigned for hearing and trial or for argument at the earliest practicable date and expedited in every way.

(E) The court may assess against the United States reasonable attorney fees and other litigation costs reasonably incurred in any case under this section in which the complainant has substantially prevailed.

(F) Whenever the court orders the production of any agency records improperly withheld from the complainant and assesses against the United States reasonable attorney fees and other litigation costs, and the court additionally issues a written finding that the circumstances surrounding the withholding raise questions whether agency personnel acted arbitrarily or capriciously with respect to the withholding, the Civil Service Commission shall promptly initiate a proceeding to determine whether disciplinary action is warranted against the officer or employee who was primarily responsible for the withholding. The Commission, after investigation and consideration of the evidence submitted, shall submit its findings and recommendations to the administrative authority

of the agency concerned and shall send copies of the findings and recommendations to the officer or employee or his representative. The administrative authority shall take the corrective action that the Commission recommends.

(G) In the event of noncompliance with the order of the court [illegible] district court may punish for contempt the responsible employee, and in the case of a uniformed service, the responsible member.

(5) Each agency having more than one member shall maintain and make available for public inspection a record of the final votes of each member in every agency proceeding.

(6)(A) Each agency, upon any request for records made under paragraph (1), (2), or (3) of this subsection, shall--

(i) determine within ten days (except Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request and shall immediately notify the person making such request of such determination and the reasons therefor, and of the right of such person to appeal to the head of the agency any adverse determination; and

(ii) make a determination with respect to any appeal within twenty days (except Saturdays, Sundays, and legal public holidays) after the receipt of such appeal. If on appeal the denial of the request for records is in whole or in part upheld, the agency shall notify the person making such request of the provisions for judicial review of that determination under paragraph (4) of this subsection.

(B) In unusual circumstances as specified in this subparagraph, the time limits prescribed in either clause (i) or clause (ii) of subparagraph (A) may be extended by written notice to the person making such request setting forth the reasons for such extension and the date on which a determination is expected to be dispatched. No such notice shall specify a date that would result in an extension for more than ten working days. As used in this subparagraph, 'unusual circumstances' means, but only to the extent reasonably necessary to the proper processing of the particular request--

(i) the need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(ii) the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(iii) the need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

(C) Any person making a request to any agency for records under paragraph (1), (2), or (3) of this subsection shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions of this paragraph. If the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records. Upon any determination by an agency to comply with a request for records, the records shall be made promptly available to such person making such request. Any notification of denial of any request for records under this subsection shall set forth the names and titles or positions of each person responsible for the denial of such requests.

(5) This section does not apply to matters that are--

(1)(A) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order;

(2) related solely to the internal personnel rules and practices of an agency;

(3) specifically exempted from disclosure by statute;

(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

(8) contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; or

(9) geological and geophysical information and data, including maps, concerning wells.

Any reasonably segregable portion of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under this subsection.

(c) This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section. This section is not authority to withhold information from Congress.

(d) On or before March 1 of each calendar year, each agency shall submit a report covering the preceding calendar year to the Speaker of the House of Representatives and President of the Senate for referral to the appropriate committees of the Congress. The report shall include--

(1) the number of determinations made by such agency not to comply with requests for records made to such agency under subsection (a) and the reasons for each such determination;

(2) the number of appeals made by persons under subsection (a)(6), the result of such appeals, and the reason for the action upon each appeal that results in a denial of information;

(3) the names and titles or positions of each person responsible for the denial of records requested under this section, and the number of instances of participation for each;

(4) the results of each proceeding conducted pursuant to subsection (a)(4)(F), including a report of the disciplinary action taken against the officer or employee who was primarily responsible for improperly withholding records or an explanation of why disciplinary action was not taken;

(5) a copy of every rule made by such agency regarding this section;

(6) a copy of the fee schedule and the total amount of fees collected by the agency for making records available under this section; and

(7) such other information as indicates efforts to administer fully this section.

The Attorney General shall submit an annual report on or before March 1 of each calendar year which shall include for the prior calendar year a listing of the number of cases arising under this section, the exemption involved in each case, the disposition of such case, and the cost, fees, and penalties assessed under subsection (a)(4)(E), (F), and (G). Such report shall also include a description of the efforts undertaken by the Department of Justice to encourage agency compliance with this section.

(e) For purposes of this section, the term 'agency' as defined in section 551(1) of this title includes any executive department, military department, Government corporation, Government controlled corporation, or other establishment in the executive branch of the Government (including the Executive Office of the President), or any independent regulatory agency.

ATTACHMENT D -- Summary of Principal Changes in the Freedom of Information Act made by the Amendments

	Changes	Place in Amended Act
1.	Publication or alternative requirement concerning indexes of (a)(2) materials	552(a)(2)
2.	Administrative time limits and extensions, and contents of denial letters	552(a)(6)
3.	Uniform agency fees for search and duplication	552(a)(4)(A)
4.	Disciplinary proceedings for arbitrary or capricious denials	552(a)(4)(F)
5.	In camera inspection by court of requested documents	552(a)(4)(B)
6.	Shortened time to answer complaint in court	552(a)(4)(C)
7.	Attorney fees award for requesters who prevail	552(a)(4)(E)
8.	Revision of exemption 1 for defense and foreign policy records classified under Executive Order	552(b)(1)
9.	Revision of exemption 7 for investigatory law enforcement records	552(b)(7)
10.	Availability of "reasonably segregable portion" of record	552(b) (at end of subsection)
11.	Annual reports to Congress	552(d)

(In addition, the 1974 Amendments make a number of other changes in the Act which, for the purposes of most agencies, are believed to be generally less significant.)

Appendix III

Title 11

General Provisions

and

Professional Standards Review

§ 1320c. Congressional declaration of purpose

In order to promote the effective, efficient, and economical delivery of health care services of proper quality for which payment may be made (in whole or in part) under this chapter and in recognition of the interests of patients, the public, practitioners, and providers in improved health care services, it is the purpose of this part to assure, through the application of suitable procedures of professional standards review, that the services for which payment may be made under this chapter will conform to appropriate professional standards for the provision of health care and that payment for such services will be made—

(1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

(2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion

Aug. 14, 1935, c. 531, Title XI, § 1151, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1429.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 1989.

Library References

Social Security and Public Welfare ⇨211. C.J.S. Social Security and Public Welfare § 73.

Code of Federal Regulations

Designation of areas for professional standards review organizations, see 42 CFR 101.1 et seq.

§ 1320c-1. Professional Standards Review Organizations —Designation

(a) The Secretary shall (1) not later than January 1, 1974, establish throughout the United States appropriate areas with respect to which Professional Standards Review Organizations may be designated, and (2) at the earliest practicable date after designation of an area enter into an agreement with a qualified organization whereby such an organization shall be conditionally designated as the Professional Standards Review Organization for such area. If, on the basis of its performance during such period of conditional designation, the Secretary determines that such organization is capable of fulfilling, in a satisfactory manner, the obligations and requirements for a Professional Standards Review Organization under this part, he shall enter into an agreement with such organization designating it as the Professional Standards Review Organization for such area.

Qualified organizations eligible for designation

(b) For purposes of subsection (a) of this section, the term "qualified organization" means—

(1) when used in connection with any area—

(A) an organization (i) which is a nonprofit professional association (or a component organization thereof), (ii) which is composed of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area, (iii) the membership of which includes a substantial proportion of all such physicians in such area, (iv) which is organized in a manner which makes available professional competence to review health care services of the types and kinds with respect to which Professional Standards Review Organizations have review responsibilities under this part, (v) the membership of which is voluntary and open to all doctors of medicine or osteopathy licensed to engage in the practice of medicine or surgery in such area without requirement of membership in or payment of

dues to any organized medical society or association, and (vi) which does not restrict the eligibility of any member for service as an officer of the Professional Standards Review Organization or eligibility for and assignment to duties of such Professional Standards Review Organization, or, subject to subsection (c)(i) of this section,

(B) such other public, nonprofit private, or other agency or organization, which the Secretary determines, in accordance with criteria prescribed by him in regulations, to be of professional competence and otherwise suitable; and

(2) an organization which the Secretary, on the basis of his examination and evaluation of a formal plan submitted to him by the association, agency, or organization (as well as on the basis of other relevant data and information), finds to be willing to perform and capable of performing, in an effective, timely, and objective manner and at reasonable cost, the duties, functions, and activities of a Professional Standards Review Organization required by or pursuant to this part.

Order of eligibility; renewal of agreements

(c)(1) The Secretary shall not enter into any agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b)(1)(A) of this section prior to January 1, 1976, nor after such date, unless, in such area, there is no organization referred to in subsection (b)(1)(A) of this section which meets the conditions specified in subsection (b)(2) of this section.

(2) Whenever the Secretary shall have entered into an agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b)(1)(A) of this section, he shall not renew such agreements with such organization if he determines that—

(A) there is in such area an organization referred to in subsection (b)(1)(A) of this section which (i) has not been previously designated as a Professional Standards Review Organization, and (ii) is willing to enter into an agreement under this part under which such organization would be designated as the Professional Standards Review Organization for such area;

(B) such organization meets the conditions specified in subsection (b)(2) of this section; and

(C) the designation of such organization as the Professional Standards Review Organization for such area is anticipated to result in substantial improvement in the performance in such area of the duties and functions required of such organizations under this part.

Agreement expiration; prior termination

(d) Any such agreement under this part with an organization (other than an agreement established pursuant to section 1320c-3 of this title) shall be for a term of 12 months; except that, prior to the expiration of such term such agreement may be terminated

(1) by the organization at such time and upon such notice to the Secretary as may be prescribed in regulations (except that notice of more than 3 months may not be required); or

(2) by the Secretary at such time and upon such reasonable notice to the organization as may be prescribed in regulations, but only after the Secretary has determined (after providing such organization with an opportunity for a formal hearing on the matter) that such organization is not substantially complying with or effectively carrying out the provisions of such agreement.

Waiver of those review, certification, and similar activities now covered by Professional Standards Review Organizations

(e) In order to avoid duplication of functions and unnecessary review and control activities, the Secretary is authorized to waive any or all of the review, certification, or similar activities otherwise required under or pursuant to any provision of this chapter (other than this part) where he finds, on the basis of substantial evidence of the effective performance of review and control activities by Professional Standards Review Organizations, that the review, certification, and similar activities otherwise so required are not needed for the provision of adequate review and control.

Agreement notice; objection by doctors; poll

(f)(1) In the case of agreements entered into prior to January 1, 1976, under this part under which any organization is designated as the Professional Standards Review Organization for any area, the Secretary shall, prior to entering into any such agreement with any organization for any area, inform (under regulations of the Secretary) the doctors of medicine or osteopathy who are in active practice in such area of the Secretary's intention to enter into such an agreement with such organization.

(2) If, within a reasonable period of time following the serving of such notice, more than 10 per centum of such doctors object to the Secretary's entering into such an agreement with such organization on the ground that such organization is not representative of doctors in such area, the Secretary shall conduct a poll of such doctors to determine whether or not such organization is representative of such doctors in such area. If more than 50 per centum of the doctors responding to such poll indicate that such organization is not

representative of such doctors in such area the Secretary shall not enter into such an agreement with such organization.

Aug. 14, 1935, c. 531, Title XI, § 1152, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1430.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-2. Review pending designation of Professional Standards Review Organization

Pending the assumption by a Professional Standards Review Organization for any area, of full review responsibility, and pending a demonstration of capacity for improved review effort with respect to matters involving the provision of health care services in such area for which payment (in whole or in part) may be made, under this chapter, any review with respect to such services which has not been designated by the Secretary as the full responsibility of such organization, shall be reviewed in the manner otherwise provided for under law.

Aug. 14, 1935, c. 531, Title XI, § 1153, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1432.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-3. Trial period for Professional Standards Review Organizations

(a) The Secretary shall initially designate an organization as a Professional Standards Review Organization for any area on a conditional basis with a view to determining the capacity of such organization to perform the duties and functions imposed under this part on Professional Standards Review Organizations. Such designation may not be made prior to receipt from such organization and approval by the Secretary of a formal plan for the orderly assumption and implementation of the responsibilities of the Professional Standards Review Organization under this part.

(b) During any such trial period (which may not exceed 24 months), the Secretary may require a Professional Standards Review Organization to perform only such of the duties and functions required under this part of Professional Standards Review Organization as he determines such organization to be capable of performing. The number and type of such duties shall, during the trial period, be progressively increased as the organization becomes capable

of added responsibility so that, by the end of such period, such organization shall be considered a qualified organization only if the Secretary finds that it is substantially carrying out in a satisfactory manner, the activities and functions required of Professional Standards Review Organizations under this part with respect to the review of health care services provided or ordered by physicians and other practitioners and institutional and other health care facilities, agencies, and organizations. Any of such duties and functions not performed by such organization during such period shall be performed in the manner and to the extent otherwise provided for under law.

(c) Any agreement under which any organization is conditionally designated as the Professional Standards Review Organization for any area may be terminated by such organization upon 90 days notice to the Secretary or by the Secretary upon 90 days notice to such organization.

Aug. 14, 1935, c. 531, Title XI, § 1154, as added Oct. 30, 1972, Pub.L. 92–603, Title II, § 249F(b), 86 Stat. 1432.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-4. Duties and functions of Professional Standards Review Organizations—Responsibility for review of professional activities; case criteria; patient profiles; physician review of hospital care; involvement of reviewing physicians

(a)(1) Notwithstanding any other provision of law, but consistent with the provisions of this part, it shall (subject to the provisions of subsection (g) of this section) be the duty and function of each Professional Standards Review Organization for any area to assume, at the earliest date practicable, responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this chapter for the purpose of determining whether—

(A) such services and items are or were medically necessary;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

(2) Each Professional Standards Review Organization shall have the authority to determine, in advance, in the case of—

(A) any elective admission to a hospital, or other health care facility, or

(B) any other health care service which will consist of extended or costly courses of treatment,

whether such service, if provided, or if provided by a particular health care practitioner or by a particular hospital or other health care facility, organization, or agency, would meet the criteria specified in clauses (A) and (C) of paragraph (1).

(3) Each Professional Standards Review Organization shall, in accordance with regulations of the Secretary, determine and publish, from time to time, the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order most effectively to carry out the purposes of this part, exercise the authority conferred upon it under paragraph (2).

(4) Each Professional Standards Review Organization shall be responsible for the arranging for the maintenance of and the regular review of profiles of care and services received and provided with respect to patients, utilizing to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part. Profiles shall also be regularly reviewed on an ongoing basis with respect to each health care practitioner and provider to determine whether the care and services ordered or rendered are consistent with the criteria specified in clauses (A), (B), and (C) of paragraph (1).

(5) Physicians assigned responsibility for the review of hospital care may be only those having active hospital staff privileges in at least one of the participating hospitals in the area served by the Professional Standards Review Organization and (except as may be otherwise provided under subsection (e)(1) of this section) such physicians ordinarily should not be responsible for, but may participate in the review of care and services provided in any hospital in which such physicians have active staff privileges.

(6) No physician shall be permitted to review—

(A) health care services provided to a patient if he was directly or indirectly involved in providing such services, or

(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has,

directly or indirectly, any financial interest in such institution, organization, or agency.

For purposes of this paragraph, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

Utilization of practitioners and specialists; examination of records; inspection of facilities

(b) To the extent necessary or appropriate for the proper performance of its duties and functions, the Professional Standards Review Organization serving any area is authorized in accordance with regulations prescribed by the Secretary to—

(1) make arrangements to utilize the services of persons who are practitioners of or specialists in the various areas of medicine (including dentistry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization;

(2) undertake such professional inquiry either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review under subsection (a)(1) of this section;

(3) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under subsection (a)(1) of this section; and

(4) inspect the facilities in which care is rendered or services provided (which are located in such area) of any practitioner or provider.

Utilization of services of unlicensed doctors of medicine or osteopathy

(c) No Professional Standards Review Organization shall utilize the services of any individual who is not a duly licensed doctor of medicine or osteopathy to make final determinations in accordance with its duties and functions under this part with respect to the professional conduct of any other duly licensed doctor of medicine or osteopathy, or any act performed by any duly licensed doctor of medicine or osteopathy in the exercise of his profession.

Familiarization of physicians with review functions of Professional Standards Review Organizations

(d) In order to familiarize physicians with the review functions and activities of Professional Standards Review Organizations and to promote acceptance of such functions and activities by physicians, patients, and other persons, each Professional Standards Review Organization, in carrying out its review responsibilities, shall (to the maximum extent consistent with the effective and timely performance of its duties and functions)

(1) encourage all physicians practicing their profession in the area served by such Organization to participate as reviewers in the review activities of such Organizations;

(2) provide rotating physician membership of review committees on an extensive and continuing basis;

(3) assure that membership on review committees have the broadest representation feasible in terms of the various types of practice in which physicians engage in the area served by such Organization; and

(4) utilize, whenever appropriate, medical periodicals and similar publications to publicize the functions and activities of Professional Standards Review Organizations.

Review committees of hospitals or other operating health care facilities or organizations

(e)(1) Each Professional Standards Review Organization shall utilize the services of, and accept the findings of, the review committees of a hospital or other operating health care facility or organization located in the area served by such organization, but only when and only to the extent and only for such time that such committees in such hospital or other operating health care facility or organization have demonstrated to the satisfaction of such organization their capacity effectively and in timely fashion to review activities in such hospital or other operating health care facility or organization (including the medical necessity of admissions, types and extent of services ordered, and lengths of stay) so as to aid in accomplishing the purposes and responsibilities described in subsection (a)(1) of this section, except where the Secretary disapproves, for good cause, such acceptance.

(2) The Secretary may prescribe regulations to carry out the provisions of this subsection.

Agreement requirements

(f)(1) An agreement entered into under this part between the Secretary and any organization under which such organization is designated as the Professional Standards Review Organization for any area shall provide that such organization will—

(A) perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part; and

(B) collect such data relevant to its functions and such information and keep and maintain such records in such form as

the Secretary may require to carry out the purposes of this part and to permit access to and use of any such records as the Secretary may require for such purposes.

(2) Any such agreement with an organization under this part shall provide that the Secretary make payments to such organization equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such organization in carrying out or preparing to carry out the duties and functions required by such agreement.

Review of health care services limited to health care services provided by or in institutions unless otherwise requested

(g) Notwithstanding any other provision of this part, the responsibility for review of health care services of any Professional Standards Review Organization shall be the review of health care services provided by or in institutions, unless such Organization shall have made a request to the Secretary that it be charged with the duty and function of reviewing other health care services and the Secretary shall have approved such request.

Aug. 14, 1935, c. 531, Title XI, § 1155, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1433.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

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§ 1320c-5. Norms of health care services—Development by Professional Standards Review Organizations

(a) Each Professional Standards Review Organization shall apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions (including typical lengths-of-stay for institutional care by age and diagnosis) as principal points of evaluation and review. The National Professional Standards Review Council and the Secretary shall provide such technical assistance to the organization as will be helpful in utilizing and applying such norms of care, diagnosis, and treatment. Where the actual norms of care, diagnosis, and treatment in a Professional Standards Review Organization area are significantly different from professionally developed regional norms of care, diagnosis, and treatment approved for comparable conditions, the Professional Standards Review Organization concerned shall be so informed, and in the event that appropriate consultation and discussion indicate reasonable basis for usage of other norms in the area concerned, the Professional Standards Review Organization may apply such norms in such area as are approved by the National Professional Standards Review Council.

(b) Such norms with respect to treatment for particular illnesses or health conditions shall include (in accordance with regulations of the Secretary)—

(1) the types and extent of the health care services which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care;

(2) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

Data on regional norms; preparation, distribution, review, and revision; utilization of norms

(c)(1) The National Professional Standards Review Council shall provide for the preparation and distribution, to each Professional Standards Review Organization and to each other agency or person performing review functions with respect to the provision of health care services under this chapter, of appropriate materials indicating the regional norms to be utilized pursuant to this part. Such data concerning norms shall be reviewed and revised from time to time. The approval of the National Professional Standards Review Council of norms of care, diagnosis, and treatment shall be based on its analysis of appropriate and adequate data.

(2) Each review organization, agency, or person referred to in paragraph (1) shall utilize the norms developed under this section as a principal point of evaluation and review for determining, with respect to any health care services which have been or are proposed to be provided, whether such care and services are consistent with the criteria specified in section 1320c-4(a)(1) of this title.

Certification for further inpatient care

(d)(1) Each Professional Standards Review Organization shall—

(A) in accordance with regulations of the Secretary, specify the appropriate points in time after the admission of a patient for inpatient care in a health care institution, at which the physician attending such patient shall execute a certification stating that further inpatient care in such institution will be medically necessary effectively to meet the health care needs of such patient; and

(B) require that there be included in any such certification with respect to any patient such information as may be necessary to enable such organization properly to evaluate the medi-

cal necessity of the further institutional health care recommended by the physician executing such certification.

(2) The points in time at which any such certification will be required (usually, not later than the 50th percentile of lengths-of-stay for patients in similar age groups with similar diagnoses) shall be consistent with and based on professionally developed norms of care and treatment and data developed with respect to length of stay in health care institutions of patients having various illnesses, injuries, or health conditions, and requiring various types of health care services or procedures.

Aug. 14, 1935, c. 531, Title XI, § 1156, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1435.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-6. Submission of reports by Professional Standards Review Organizations

If, in discharging its duties and functions under this part, any Professional Standards Review Organization determines that any health care practitioner or any hospital, or other health care facility, agency, or organization has violated any of the obligations imposed by section 1320c-9 of this title, such organization shall report the matter to the Statewide Professional Standards Review Council for the State in which such organization is located together with the recommendations of such Organization as to the action which should be taken with respect to the matter. Any Statewide Professional Standards Review Council receiving any such report and recommendation shall review the same and promptly transmit such report and recommendation to the Secretary together with any additional comments or recommendations thereon as it deems appropriate. The Secretary may utilize a Professional Standards Review Organization, in lieu of a program review team as specified in sections 1395y and 1395cc of this title, for purposes of subparagraph (C) of section 1395y(d)(1) of this title and subparagraph (F) of section 1395cc(b)(2) of this title.

Aug. 14, 1935, c. 531, Title XI, § 1157, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1437.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-7. Review approval as condition of payment of claims

(a) Except as provided for in section 1320c-8 of this title, no Federal funds appropriated under any subchapter of this chapter (other than subchapter V) for the provision of health care services or items shall be used (directly or indirectly) for the payment, under such subchapter or any program established pursuant thereto, of any claim for the provision of such services or items, unless the Secretary, pursuant to regulation determines that the claimant is without fault if—

(1) the provision of such services or items is subject to review under this part by any Professional Standards Review Organization, or other agency; and

(2) such organization or other agency has, in the proper exercise of its duties and functions under or consistent with the purposes of this part, disapproved of the services or items giving rise to such claim, and has notified the practitioner or provider who provided or proposed to provide such services or items and the individual who would receive or was proposed to receive such services or items of its disapproval of the provision of such services or items.

(b) Whenever any Professional Standards Review Organization, in the discharge of its duties and functions as specified by or pursuant to this part, disapproves of any health care services or items furnished or to be furnished by any practitioner or provider, such organization shall, after notifying the practitioner, provider, or other organization or agency of its disapproval in accordance with subsection (a) of this section, promptly notify the agency or organization having responsibility for acting upon claims for payment for or on account of such services or items.

Aug. 14, 1935, c. 531, Title XI, § 1158, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1437.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-8. Hearing and review by Secretary

(a) Any beneficiary or recipient who is entitled to benefits under this chapter (other than subchapter V) or a provider or practitioner who is dissatisfied with a determination with respect to a claim made by a Professional Standards Review Organization in carrying out its responsibilities for the review of professional activities in accordance with paragraphs (1) and (2) of section 1320c-4(a) of this title shall, after being notified of such determination, be entitled to a reconsideration thereof by the Professional Standards Re-

view Organization and, where the Professional Standards Review Organization reaffirms such determination in a State which has established a Statewide Professional Standards Review Council, and where the matter in controversy is $100 or more, such determination shall be reviewed by professional members of such Council and, if the Council so determined, revised.

(b) Where the determination of the Statewide Professional Standards Review Council is adverse to the beneficiary or recipient (or, in the absence of such Council in a State and where the matter in controversy is $100 or more), such beneficiary or recipent shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and, where the amount in controversy is $1,000 or more, to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. The Secretary will render a decision only after appropriate professional consultation on the matter.

(c) Any review or appeals provided under this section shall be in lieu of any review, hearing, or appeal under this chapter with respect to the same issue.

Aug. 14, 1935, c. 531, Title XI, § 1159, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1437.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-9. Obligations of health care practitioners and providers of health care services—Enumeration of obligations

(a)(1) It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this chapter, to assure that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this chapter—

(A) will be provided only when, and to the extent, medically necessary; and

(B) will be of a quality which meets professionally recognized standards of health care; and

(C) will be supported by evidence of such medical necessity and quality in such form and fashion and at such time as may reasonably be required by the Professional Standards Review Organization in the exercise of its duties and responsibilities;

and it shall be the obligation of any health care practitioner in ordering, authorizing, directing, or arranging for the provision by any

other person (including a hospital or other health care facility, organization, or agency), of health care services for any patient of such practitioner, to exercise his professional responsibility with a view to assuring (to the extent of his influence or control over such patient, such person, or the provision of such services) that such services or items will be provided—

(D) only when, and to the extent, medically necessary; and

(E) will be of a quality which meets professionally recognized standards of health care.

(2) Each health care practitioner, and each hospital or other provider of health care services, shall have an obligation, within reasonable limits of professional discretion, not to take any action, in the exercise of his profession (in the case of any health care practitioner), or in the conduct of its business (in the case of any hospital or other such provider), which would authorize any individual to be admitted as an inpatient in or to continue as an inpatient in any hospital or other health care facility unless—

(A) inpatient care is determined by such practitioner and by such hospital or other provider, consistent with professionally recognized health care standards, to be medically necessary for the proper care of such individual; and

(B)(i) the inpatient care required by such individual cannot, consistent with such standards, be provided more economically in a health care facility of a different type; or

(ii) (in the case of a patient who requires care which can, consistent with such standards, be provided more economically in a health care facility of a different type) there is, in the area in which such individual is located, no such facility or no such facility which is available to provide care to such individual at the time when care is needed by him.

Failure to comply with obligations; gross and flagrant violations; exclusion of practitioner or provider from eligibility; sanctions and penalties; hearing and review

(b)(1) If after reasonable notice and opportunity for discussion with the practitioner or provider concerned, any Professional Standards Review Organization submits a report and recommendations to the Secretary pursuant to section 1320c-6 of this title (which report and recommendations shall be submitted through the Statewide Professional Standards Review Council, if such Council has been established, which shall promptly transmit such report and recommendations together with any additional comments and recommendations thereon as it deems appropriate) and if the Secretary determines that such practitioner or provider, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this chapter has—

(A) by failing, in a substantial number of cases, substantially to comply with any obligation imposed on him under subsection (a) of this section, or

(B) by grossly and flagrantly violating any such obligation in one or more instances.

demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, he (in addition to any other sanction provided under law) may exclude (permanently for such period as the Secretary may prescribe) such practitioner or provider from eligibility to provide such services on a reimbursable basis.

(2) A determination made by the Secretary under this subsection shall be effective at such time and upon such reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of institutional health care services such determination shall be effective in the manner provided in subchapter XVIII of this chapter with respect to terminations of provider agreements), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or provider to provide such health care services on a reimbursable basis) such practitioner or provider pay to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or provider of health care services which were medically improper or unnecessary, an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided, or (if less) $5,000. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the person from whom such amount is claimed.

(4) Any person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

Duty of Review Organizations and Statewide Review Councils to assure compliance with obligations

(c) It shall be the duty of each Professional Standards Review Organization and each Statewide Professional Standards Review Council to use such authority or influence it may possess as a pro-

fessional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the area served by such review organization, in assuring that each practitioner or provider (referred to in subsection (a) of this section) providing health care services in such area shall comply with all obligations imposed on him under subsection (a) of this section.

Aug. 14, 1935, c. 531, Title XI, § 1160, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1438.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-10. Notice to practitioner or provider

Whenever any Professional Standards Review Organization takes any action or makes any determination—

(a) which denies any request, by a health care practitioner or other provider of health care services, for approval of a health care service or item proposed to be ordered or provided by such practitioner or provider; or

(b) that any such practitioner or provider has violated any obligation imposed on such practitioner or provider under section 1320c-9 of this title,

such organization shall, immediately after taking such action or making such determination, give notice to such practitioner or provider of such determination and the basis therefor, and shall provide him with appropriate opportunity for discussion and review of the matter.

Aug. 14, 1935, c. 531, Title XI, § 1161, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1440.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-11. Statewide Professional Standards Review Councils—Establishment

(a) In any State in which there are located three or more Professional Standards Review Organizations, the Secretary shall establish a Statewide Professional Standards Review Council.

Membership

(b) The membership of any such Council for any State shall be appointed by the Secretary and shall consist of—

(1) one representative from and designated by each Professional Standards Review Organization in the State;

(2) four physicians, two of whom may be designated by the State medical society and two of whom may be designated by the State hospital association of such State to serve as members on such Council; and

(3) four persons knowledgeable in health care from such State whom the Secretary shall have selected as representatives of the public in such State (at least two of whom shall have been recommended for membership on the Council by the Governor of such State).

Duties

(c) It shall be the duty and function of the Statewide Professional Standards Review Council for any State, in accordance with regulations of the Secretary, (1) to coordinate the activities of, and disseminate information and data among the various Professional Standards Review Organizations within such State including assisting the Secretary in development of uniform data gathering procedures and operating procedures applicable to the several areas in a State (including, where appropriate, common data processing operations serving several or all areas) to assure efficient operation and objective evaluation of comparative performance of the several areas and, (2) to assist the Secretary in evaluating the performance of each Professional Standards Review Organization, and (3) where the Secretary finds it necessary to replace a Professional Standards Review Organization, to assist him in developing and arranging for a qualified replacement Professional Standards Review Organization.

Payments

(d) The Secretary is authorized to enter into an agreement with any such Council under which the Secretary shall make payments to such Council equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such Council in carrying out the duties and functions provided in this section.

Advisory groups

(e)(1) The Statewide Professional Standards Review Council for any State (or in a State which does not have such Council, the Professional Standards Review Organizations in such State which have agreements with the Secretary) shall be advised and assisted in carrying out its functions by an advisory group (of not less than

seven nor more than eleven members) which shall be made up of representatives of health care practitioners (other than physicians) and hospitals and other health care facilities which provide within the State health care services for which payment (in whole or in part) may be made under any program established by or pursuant to this chapter.

(2) The Secretary shall by regulations provide the manner in which members of such advisory group shall be selected by the Statewide Professional Standards Review Council (or Professional Standards Review Organizations in States without such Councils).

(3) The expenses reasonably and necessarily incurred, as determined by the Secretary, by such group in carrying out it[1] duties and functions under this subsection shall be considered to be expenses necessarily incurred by the Statewide Professional Standards Review Council served by such group.

Aug. 14, 1935, c. 531, Title XI, § 1162, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1440.

[1] So in original. Probably should read "its".

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-12. National Professional Standards Review Council—Establishment; membership

(a)(1) There shall be established a National Professional Standards Review Council (hereinafter in this section referred to as the "Council") which shall consist of eleven physicians, not otherwise in the employ of the United States, appointed by the Secretary without regard to the provisions of Title 5 governing appointments in the competitive service.

(2) Members of the Council shall be appointed for a term of three years and shall be eligible for reappointment.

(3) The Secretary shall from time to time designate one of the members of the Council to serve as Chairman thereof.

Qualifications for membership

(b) Members of the Council shall consist of physicians of recognized standing and distinction in the appraisal of medical practice. A majority of such members shall be physicians who have been recommended by the Secretary to serve on the Council by national organizations recognized by the Secretary as representing practicing physicians. The membership of the Council shall include physicians who have been recommended for membership on the Council by consumer groups and other health care interests.

Consultants

(c) The Council is authorized to utilize, and the Secretary shall make available, or arrange for, such technical and professional consultative assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Council such secretarial, clerical and other assistance and such pertinent data prepared by, for, or otherwise available to, the Department of Health, Education, and Welfare as the Council may require to carry out its functions.

Compensation of members

(d) Members of the Council, while serving on business of the Council, shall be entitled to receive compensation at a rate fixed by the Secretary (but not in excess of the daily rate paid under GS-18 of the General Schedule under section 5332 of Title 5), including traveltime; and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of Title 5 for persons in Government service employed intermittently.

Duties

(e) It shall be the duty of the Council to—

(1) advise the Secretary in the administration of this part;

(2) provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions;

(3) review the operations of Statewide Professional Standards Review Councils and Professional Standards Review Organizations with a view to determining the effectiveness and comparative performance of such review councils and organizations in carrying out the purposes of this part; and

(4) make or arrange for the making of studies and investigations with a view to developing and recommending to the Secretary and to the Congress measures designed more effectively to accomplish the purposes and objectives of this part.

Reports

(f) The National Professional Standards Review Council shall from time to time, but not less often than annually, submit to the Secretary and to the Congress a report on its activities and shall include in such report the findings of its studies and investigations together with any recommendations it may have with respect to the more effective accomplishment of the purposes and objectives of this part. Such report shall also contain comparative data indicat-

ing the results of review activities, conducted pursuant to this part, in each State and in each of the various areas thereof.

Aug. 14, 1935, c. 531, Title XI, § 1163, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1441.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-13. Professional standards review requirements applicable to certain State programs

(a) In addition to the requirements imposed by law as a condition of approval of a State plan approved under any subchapter of this chapter under which health care services are paid for in whole or part, with Federal funds, there is hereby imposed the requirement that provisions of this part shall apply to the operation of such plan or program.

(b) The requirement imposed by subsection (a) of this section with respect to such State plans approved under this chapter shall apply—

(1) in the case of any such plan where legislative action by the State legislature is not necessary to meet such requirement, on and after January 1, 1974; and

(2) in the case of any such plan where legislative action by the State legislature is necessary to meet such requirement, whichever of the following is earlier—

(A) on and after July 1, 1974, or

(B) on and after the first day of the calendar month which first commences more than ninety days after the close of the first regular session of the legislature of such State which begins after December 31, 1973.

Aug. 14, 1935, c. 531, Title XI, § 1164, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1442.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-14. Correlation of functions between Professional Standards Review Organizations and administrative instrumentalities

The Secretary shall by regulations provide for such correlation of activities, such interchange of data and information, and such other cooperation consistent with economical, efficient, coordinated, and comprehensive implementation of this part (including, but not limit-

ed to, usage of existing mechanical and other data-gathering capacity) between and among—

(a)(1) agencies and organizations which are parties to agreements entered into pursuant to section 1395h of this title, (2) carriers which are parties to contracts entered into pursuant to section 1395u of this title, and (3) any other public or private agency (other than a Professional Standards Review Organization) having review or control functions, or proved relevant data-gathering procedures and experience, and

(b) Professional Standards Review Organizations, as may be necessary or appropriate for the effective administration of subchapter XVIII of this chapter, or State plans approved under this chapter.

Aug. 14, 1935, c. 531, Title XI, § 1165, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1443.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-15. Disclosure of information prohibited

(a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.

(b) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than six months, or both, together with the costs of prosecution.

Aug. 14, 1935, c. 531, Title XI, § 1166, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1443.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-16. Limitation of liability—Persons providing information to Professional Standards Review Organizations

(a) Notwithstanding any other provision of law, no person providing information to any Professional Standards Review Organization shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) unless—

(1) such information is unrelated to the performance of the duties and functions of such Organization, or

(2) such information is false and the person providing such information knew, or had reason to believe, that such information was false.

Members and employees of Professional Standards Review Organizations

(b)(1) No individual who, as a member or employee of any Professional Standards Review Organization or who furnishes professional counsel or services to such organization, shall be held by reason of the performance by him of any duty, function, or activity authorized or required of Professional Standards Review Organizations under this part, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) provided he has exercised due care.

(2) The provisions of paragraph (1) shall not apply with respect to any action taken by any individual if such individual, in taking such action, was motivated by malice toward any person affected by such action.

Health care practitioners and providers

(c) No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization (which has been designated in accordance with section 1320c-1(b)(1)(A) of this title) operating in the area where such doctor of medicine or osteopathy or provider took such action but only if—

(1) he takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment.

Aug. 14, 1935, c. 531, Title XI, § 1167, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1443.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-17. Authorization for use of funds to administer professional standards review program

Expenses incurred in the administration of this part shall be payable from—

(a) funds in the Federal Hospital Insurance Trust Fund;

(b) funds in the Federal Supplementary Medical Insurance Trust Fund; and

(c) funds appropriated to carry out the health care provisions of the several subchapters of this chapter;

in such amounts from each of the sources of funds (referred to in subsections (a), (b), and (c) of this section) as the Secretary shall deem to be fair and equitable after taking into consideration the costs attributable to the administration of this part with respect to each of such plans and programs.

Aug. 14, 1935, c. 531, Title XI, § 1168, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1444.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-18. Technical assistance to organizations desiring to be designated as Professional Standards Review Organizations

The Secretary is authorized to provide all necessary technical and other assistance (including the preparation of prototype plans of organization and operation) to organizations described in section 1320c-1(b)(1) of this title which—

(a) express a desire to be designated as a Professional Standards Review Organization; and

(b) the Secretary determines have a potential for meeting the requirements of a Professional Standards Review Organization;

to assist such organizations in developing a proper plan to be submitted to the Secretary and otherwise in preparing to meet the requirements of this part for designation as a Professional Standards Review Organization.

Aug. 14, 1935, c. 531, Title XI, § 1169, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1444.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

§ 1320c-19. Exemptions of Christian Science sanatoriums

The provisions of this part shall not apply with respect to a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts.

Aug. 14, 1935, c. 531, Title XI, § 1170, as added Oct. 30, 1972, Pub.L. 92-603, Title II, § 249F(b), 86 Stat. 1445.

Historical Note

Legislative History. For legislative history and purpose of Pub.L. 92-603, see 1972 U.S.Code Cong. and Adm.News, p. 4989.

SUBCHAPTER XII—ADVANCES TO STATE UNEMPLOYMENT FUNDS

§ 1321. Eligibility requirements for transfer of funds; reimbursement by State; application; certification; limitation

(a)(1) Advances shall be made to the States from the Federal unemployment account in the Unemployment Trust Fund as provided in this section, and shall be repayable, without interest, in the manner provided in sections 1101(d)(1), 1103(b)(2), and 1322 of this title. An advance to a State for the payment of compensation in any month may be made if—

(A) the Governor of the State applies therefor no earlier than the first day of the preceding month, and

(B) he furnishes to the Secretary of Labor his estimate of the amount of an advance which will be required by the State for the payment of compensation in such month.

(2) In the case of any application for an advance under this section to any State for any month, the Secretary of Labor shall—

(A) determine the amount (if any) which he finds will be required by such State for the payment of compensation in such month, and